

## DOCTOR OF PHILOSOPHY

Longitudinal evaluation of 'Navigation', a decision support intervention for patients with colorectal cancer and high grade glioma  
**a mixed methods study**

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# Longitudinal evaluation of 'Navigation', a decision support intervention for patients with Colorectal Cancer and High Grade Glioma: A Mixed Methods study.

**By**

**Sarah C Shepherd**

**PhD**

**May 2016**



***A thesis submitted in partial fulfilment of the University's requirements for the Degree of Doctor of Philosophy.***

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## **Acknowledgements**

In acknowledging the many important people who have played a role in this thesis I must acknowledge the passage of time this thesis represents. And so I begin with my Nan and grandpa, who watched me start but not finish – and who never doubted I wouldn't. To my mum and my dad, I am thankful and stirred by their unfaltering and endless love, support and guidance. To my brother and sister who support me regardless. To my family and friends who are always there, and to my partner, for his complete and utter belief in me, no matter what.

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## **Abstract**

**Introduction:** At the core of UK policy for improving outcomes in cancer are goals for a healthcare where patients are empowered through information enabling engagement in shared care decisions with clinicians. Interventions to support patients' engagement in shared decision making are lacking within colorectal cancer and high grade glioma care despite intensive treatment regimens with uncertain outcomes. Navigation, a communication and decision support intervention, has been successfully piloted with prostate and breast cancer patients who demonstrated significantly more confidence and less uncertainty in their treatment decisions. With healthcare policy advocating patients be educated and engaged in their care, the applicability of this intervention to other cancer settings is required. The Navigation intervention includes: consultation planning with a Navigator, formulation of a consultation plan and recording (summary and CD) of the medical consultation.

**Objectives:** To determine the effectiveness of the Navigation intervention in enhancing decision-making quality over time when compared with usual care, in patients with colorectal cancer. To explore repeated experiences of the Navigation intervention from the perspective of colorectal cancer (CRC) patients, patients with high grade glioma (HGG), and consulting clinicians.

**Design and Studies:** A mixed methods study using a pragmatic randomised controlled trial and qualitative evaluation was undertaken during November 2010 – December 2013. The intervention was trialled separately with two cohorts of cancer patients (CRC and HGG). A longitudinal parallel-group pragmatic randomised controlled trial was conducted. Study 1 consisted of a longitudinal parallel-group pragmatic randomised control trial. Participants with colorectal cancer were openly randomised after completion of baseline measures to receive the intervention or usual care (no intervention). The intervention was administered to patients at three particular time points during first line cancer treatment. Participants

completed tools collecting primary outcome (decision self-efficacy) and secondary outcomes (decision conflict, decision regret, anxiety and depression) measured prior to baseline, post consultation and at follow-up. Mean change in scores overtime and between groups were compared using Mixed ANOVAS. Study two was a prospective qualitative study undertaking serial in-depth semi-structured evaluation interviews with patients with High Grade Glioma. Study three undertook interviews with the consulting HGG and CRC clinicians. Framework analysis was undertaken.

**Setting:** Two oncology settings within a tertiary cancer centre in Scotland.

**Participants:** 132 patients with colorectal cancer (65 intervention, 67 control) participated in the randomised controlled trial. For the qualitative study, 17 colorectal trial participants (8 intervention, 9 control), 11 high grade glioma patients and 7 clinicians were interviewed.

**Evaluation Results:** No significant difference was found between the control and Navigation intervention participants over time in the primary outcome of decision self-efficacy, or in the following secondary outcomes; decision conflict or anxiety and depression scores. At follow-up, the intervention group reported significantly less decision regret than the controls ( $p=0.039$ ). In the qualitative data, Navigated participants reported being well prepared for medical consultations, able to actively engage in information exchange during consultation and enabled to recall and understand information provided. This was in contrast to participants receiving usual care who described being less prepared for medical consultations and experienced barriers to gathering information, such as time pressures, forgetting questions, and gaps in understanding. Clinicians identified that patients benefitted from preparing for, and having a written summary of, the consultation. Whereas neuro-oncology clinicians were supportive of Navigation as a tool to tailor information to patients; colorectal clinicians felt Navigation was a disruption to their normal consultation routine. Concern was

expressed regarding the extra resource required by Navigated patients and therefore about the feasibility and sustainability of the intervention.

**Conclusions:** Whilst models of shared decision making remain highly profiled in cancer strategies, information exchange and use of interventions in context is problematic. This evaluation of Navigation has demonstrated more impact on the process of decision making, rather than outcome per se, and has raised questions about its sustainability in clinical practice. A more nuanced understanding of different cancer pathways and the specific decisions to be made, may inform a more targeted use of decision support in cancer care.

## **Dissemination**

Findings from this thesis were presented at the following conferences:

Shepherd SC, Hacking B, Wallace LM, Belkora, J. 2014 Health providers' evaluation of Decision Navigation: Does it work well with my practice? Oral Presentation, International Conference On Communication In Healthcare, (EACH) 29 September – 1 October 2014, Amsterdam, Netherlands.

Shepherd SC, Wallace LM, Hacking B, Scott SE and Belkora, J. Preliminary RCT results of Decision Navigation, for patients with colorectal cancer. Oral Presentation, International Conference on Communication in Healthcare, (EACH) 29 September – 1 October 2014, Amsterdam, Netherlands.

Shepherd SC, Wallace LM, Hacking B, Scott SE and Bowyer DJ. Navigation' for High Grade brain tumour patients. A longitudinal qualitative evaluation of a shared decision making intervention. Oral Presentation. International Psycho-oncology society (IPOS), Rotterdam, 4-8 November, 2013

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Shepherd, S.C., Cavers, D., Scott, S.E., Bowyer, D., Wallace L.M., & Hacking B. Navigation' a communication aid for high grade brain tumour patients at key pathway decision points. A qualitative evaluation. Oral Presentation, International Conference On Communication In Healthcare, (EACH) 4-7 September 2012, University of St Andrews, Scotland, UK

Sarah Shepherd, Belinda Hacking, Debbie Cavers, Sarah Scott, and Debra Bowyer. The experiences of a decision support intervention, Navigation, in patients with a High Grade Glioma; a qualitative study. NHS Lothian Psychology Conference, June 2012

Shepherd, S., Dennahy, I., Leese, C., Lyell, I., Mathur, A., McKean, G., Nott, J., Ventre, C. & Waddell, J. The impact of a tertiary centre patient support intervention, 'Navigation' on primary care; A qualitative evaluation. Primary Care Fringe Session Poster Presentation,

NHS Scotland Conference. Scottish Exhibition & Conference Centre, Glasgow. 21-22nd June 2012.

Shepherd, S.C., Cavers, D., Scott, S.E., Bowyer, D., Wallace, L.M., Hacking B. 'Navigation' to support decision making for patients with a high grade brain tumour. A qualitative evaluation. Poster Presentation, British Neuro-Oncology Society (BNOS), Manchester, June 2012

Shepherd, S.C., Scott, S.E., Bowyer, D., Wallace, L.M & Hacking, B. Tailoring Decision Navigation to Primary Malignant Brain Tumour Patient's needs. Poster Presentation, British Neuro-Oncology Society (BNOS), Cambridge, June 2011

Shepherd, S.C., Scott, S.E., Bowyer, D., Wallace, L.M. Intervention development: Combining Antecedent, Target, Measurement and Intervention Mapping to develop the 'Decision Navigation' intervention for brain tumour patients. 7th Annual Scientific Meeting of the UK Society for Behavioural Medicine, UKSBM, University of Stirling 13/14 December 2011.

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## **Chapter 1: Introduction**

### **1.1. Overview**

Chapter 1 sets out the context and rationale for this research study. By situating the need for decision support in specific cancer populations, justification for the study and for the study aims and objectives is presented. The chapter closes with a description of structure of this thesis.

### **1.2. Study Context and Rationale**

Cancer places a considerable burden on societies and individuals worldwide. In 2012, there were 14.1 million new cancer cases reported worldwide, 8.2 million cancer deaths and 32.6 million people known to be living with cancer within 5 years of diagnosis (Torre et al., 2015). In reviewing United Kingdom (UK) statistics for the same time period 157,849 cancer patients died and 327,812 people were diagnosed with cancer (Torre et al., 2015) indicating that 0.76% of the UK population (based on World Bank data, 2014) had, or died from cancer during this time. Whilst it could be argued that cancer therefore holds a small disease profile in the UK, it is predicted that the rates of cancer are set to rise over the coming decade (Ferley et al., 2015).

Cancer is a proliferative disease. Currently more than 200 different forms of cancer exist, although in the UK, four types of cancer, namely breast, lung, prostate and colorectal, account for over half (53%) of all new cases (Siegel, Naishadham, & Jemal, 2013). While malignant tumours can occur at any age, cancer is predominately a disease of older people with more than half of all new cancer cases in the UK diagnosed in people aged 65 and over (Siegel et al, 2013). Given that the number of older cancer patients is set to double by 2030

(Jemal, Siegel, Xu & Ward, 2010), this is a further and important factor that contributes to the on-going global burden of this disease.

Though cancer retains its reputation as a feared disease, cancer survivorship is an area of increasing clinical and empirical interest. Improvements in treatment, early diagnosis and public awareness have meant that cancer mortality rates in the UK have decreased by more than a fifth (23%) since the mid-1980s (Cancer Research UK, 2014). With increasing numbers of people living with, and surviving cancer (Maddams et al., 2009), the fiscal and resource impact of this disease is well recognised. The annual cost of cancer services to the National Health Service is estimated at £5 billion with the cost to society as a whole, including loss of productivity, estimated at £18.3 billion (Department of Health (DH), 2011). Indeed, these costs can only be set to rise as the incidence of cancer increases, as people live longer with cancer, and as new treatments become available (Featherstone & Whitham, 2010). Perhaps most concerning given such investment, is the knowledge that patient cancer outcomes in England are poor when compared with outcomes in parts of Europe (DH, 2011).

Whilst much cancer research is focussed on medical treatment and management, there has been increasing empirical, health policy and consumer interest in how having a cancer diagnosis, undergoing cancer treatment, and indeed living with (and for some, dying from cancer) impacts on the individual. This has been informed by the concept of patient-centred care and shared decision making (SDM) that is now well embedded in health care policy and commentary (DH, 2010a; Coulter & Collins, 2011). The last decade has seen a shift in health policy now seeking to place patients at the heart of health care through the mechanisms of shared decision making, information provision, patient feedback and public accountability (for example, DH, 2010b). This same focus on patient-centred care can also be seen at the

core of UK policy for improving cancer outcomes; here the same principles are visible whereby it is envisioned that patients are empowered through having information that enables full engagement in their care decisions together with the clinicians (DH, 2011). This in turn, has led to improved engagement and more active working with patients and service users as evidenced by the BIG Cancer Conversation work in Scotland (Healthcare Policy & Strategy Directorate Living with Cancer Group, 2009) that outlines how cancer patients can become genuine partners in decision making about their care.

Despite worldwide recognition of the importance of patients being partners in care and for patients to have access to high quality information to guide treatment decisions (British Medical Journal, 2011), patient decision making in cancer is complex. There is potential for many emotional, psychological, physical and practical challenges during the cancer treatment and disease trajectory, in addition to a range of decisions to be made including those concerning cancer treatment, symptom control and even supportive care. There may be situations leading to uncertain outcomes, and the consequences of successful treatment may need weighing against the risk of severe side effects (Shaha, Cox, Talman & Kelly, 2008).

It is therefore unsurprising that against this complex decision making backdrop the patient voice is heterogeneous, with a range of opinions on the role of patients in decision making about their own health care. Whilst some studies indicate most cancer patients want engagement and access to all information (Jenkins, Fallowfield, & Saul, 2001) with full involvement in decision making (Coulter & Jenkinson, 2005), other research offers a different view reporting that preference for participating in decision making varies greatly amongst individuals and over time (De Heas, 2006; Leydon et al., 2000). This may be influenced by factors such as a desire to place trust in medical decision making, therefore



potentially preserving hope for survival (Leydon et al., 2000) or as a mechanism to reduce potential regret about decisions made (Schwartz, 2004). However, what emerges from the literature is that whatever position is held, many people with cancer do not achieve their desired level of involvement in decision making and look back on their treatment decision process with regret (Brehaut et al., 2003).

Shared decision making (SDM) is one approach that seeks to mitigate such patient concerns. SDM encompasses an active exchange of information and dialogue between the clinician and the patient to work towards a goal of a mutually agreed treatment decision. Engagement in the SDM process can help to improve patient understanding, satisfaction and confidence in the decisions made (Edwards & Elwyn, 2006). However, despite its emphasis in national and international policy and practice initiatives, the use of SDM is rarely observed in ‘real life’ clinical practice (Karnieli-Miller & Eisikovits, 2009; Lipstein Dodds & Britto, 2014). Consequently, a number of interventions to facilitate SDM have been developed and broadly include such approaches as: decision aids, question prompt sheets; coaching; and provision of a recording and/or summary of the consultation (Stacey et al., 2014). A recent Cochrane review explored the effectiveness of these techniques with particular focus on the outcomes of increasing question-asking in consultations, increasing patient recall of information discussed, and increasing patient satisfaction and patient confidence in treatment decisions (Stacey et al., 2011). Whilst this review demonstrates that SDM interventions improved knowledge, involvement and perception of outcomes, there is concern that SDM is only significant if there is a ‘meaningful’ conversation between the clinician and patient (Epstein & Gramling, 2013) with the patient engaging with, and having addressed their health care concerns.

To take on this active role in health care, patients require a sense of control over events relating to their health and healthcare (Bandura, 1994). Three of the SDM intervention approaches described above, namely, question listing, audio recording and summarising are evidence based practices which underpin a particular patient-centred communication intervention, referred to as Navigation. With an aim of facilitating patient-doctor communication and patient decision making, Navigation has been well-utilised and successfully evaluated in breast cancer consultations in the United States of America (Belkora 2008; Belkora 2008b; Belkora et al. 2009) and prostate cancer consultations in Scotland (Hacking et al., 2013). Use of the Navigation tool in these studies has significantly reduced patient-reported communication barriers in the medical consultation (Sepucha, Belkora, Mutchnick, & Esserman, 2002) and significantly increased patient reported confidence in decision making (Hacking et al., 2013). Prior experiences with CPRS (Consultation Planning, Recording and Summarising) established its feasibility and effectiveness across a broad range of clinical conditions. The present work seeks to extend this body of evidence within oncology. To date, Navigation has only been evaluated at one time point in the cancer journey, and with only a limited number of cancer populations. Longitudinal studies are lacking and this is a significant omission given that treating cancer can be a lengthy process with multiple treatment decisions to be made throughout the disease course. This thesis seeks to address this gap by evaluating the use of the navigation tool in two cancer populations with different disease trajectories and different patient information needs.

The first population is patients with colorectal cancer, the fourth most common cancer in the UK accounting for 13% of all new cancer cases (Cancer research UK, 2010). It is a cancer with a well-established treatment pathway and 45% survival rates five years following

diagnosis. The second population is patients with a High Grade Glioma (HGG). This, in contrast is a rare cancer with no current treatments for improving life expectancy (Cancer Research UK, 2009). Receiving a diagnosis of HGG is therefore devastating and distressing for patients and their families (Janda, Eakin, Bailey, Walker & Troy, 2006; Keime-Guibert, et al., 2007). As treatment is limited, non-clinical aspects of care such as communication and support practices are an important component of health care for these patients and their families (Catt, Chalmers & Fallowfield, 2008) and yet, information for HGG patients and families is more limited (Adelbratt & Strang, 2000). Furthermore, there is little SDM research undertaken with the population (Davies & Higginson, 2003).

### **1.3. Aim and Objectives**

The aim of this study is to evaluate the effectiveness of the Navigation intervention in two different cancer populations: patients diagnosed with colorectal cancer and patient diagnosed with high grade glioma. The aims of the thesis are to:

- determine the effectiveness of the Navigation intervention in enhancing decision-making quality (increasing self-efficacy, reducing decision conflict and decision regret) in patients with colorectal cancer over time from baseline (pre-initial consultation) through to and including follow-up when compared with usual care.
- explore experiences of the Navigation intervention from the perspective of patients with high grade glioma and with colorectal patients, contrasting this with colorectal patients' experience of usual care.
- explore experiences of the Navigation intervention from the perspective of colorectal cancer consultants and high grade glioma clinicians.
- make recommendations about the applicability of Navigation within cancer care and the wider health care arena.

#### **1.4. The structure of the thesis**

This chapter has set out the rationale, justification and aims of this thesis. The chapter structure of this thesis is outlined below.

Chapter 2 provides a background to the two oncology populations (CRC and HGG) studied in this thesis. It contextualises the challenges inherent in receiving the specific cancer diagnosis, the possible treatments and care pathways. It further reports what is empirically known about the information needs and decision making preferences of these patient groups, and provides a justification for the need for decision support.

Chapter 3 provides in-depth discussion of the theoretical, conceptual and empirical evidence base of shared decision making in health, specifically in medical consultations. Shared decision making models, related health policy context, barriers to decision making and decision support technologies are examined. Drawing on the importance of patient involvement in care, the chapter provides a narrative review of the literature about cancer patients' information needs and decision making preferences.

Chapter 4 introduces the over-arching study design and provides methodological discussion and critique of the mixed methods used to evaluate the Navigation intervention in the two cancer populations: the colorectal and high grade glioma cohorts. The two cancer populations are described in-depth and the Navigation intervention is detailed. The two studies used to evaluate impact of the intervention, the randomised controlled trial and qualitative study will also be introduced. The study ethics will also be discussed.

Chapters 5 and 6 describe the design and results of the randomised controlled trial conducted to evaluate Navigation within the colorectal population. Chapter 5 details the research methods: the setting, recruitment, data collection and analysis. Chapter 6 presents results from the randomised controlled trial, including results from the intervention and control groups across multiple time points.

The following three chapters present the methods and findings of the qualitative components of the evaluation: qualitative interviews with colorectal trial participants, high grade glioma participants, their carers, and their health care professionals. Chapter 7 explores the methodological and ethical challenges of conducting interviews to evaluate the intervention with a sample of colorectal trial participants and a cohort of patients with high grade glioma. Chapter 8 reports the analysis of the qualitative interviews conducted with participants and their carers and Chapter 9 presents analysis of the healthcare professional interviews. These chapters therefore present and contrast results across those participants experiencing Navigation and those receiving standard care, and across patient and health care professional groups.

Chapter 10 draws together all results from the studies and critically discusses how these add to and challenge the current evidence base on shared decision making in medical and health care consultations. The strengths and weaknesses of the study designs and methods used are also discussed.

Chapter 11 draws the thesis to a close with final commentary on the results making suggestions for further research, and presents recommendations to improve patient care and health policy for patients with cancer.

## **Chapter 2: Colorectal and high grade glioma cancer populations: care pathways, information and decision-making needs.**

### **2.1. Overview**

This chapter begins by setting out the context and rationale for this research, through description of the cancer population, and in particular the cancer populations that are the focus of this thesis: people with colorectal cancer and high grade glioma. Following information about disease incidence, staging and prognosis, and treatment, research concerning support and coping with these conditions is given. Finally, the specific issues of decision making and information needs for each of these populations is explored. This chapter concludes by drawing on the generic cancer literature to situate the CRC and HGG population specific literature in the wider cancer context.

The literature review undertaken to inform the population-specific literature was exploratory in nature. Although a structured approach was undertaken, it did not adhere to conventional systematic review methodology. Relevant literature was identified by searching Pubmed, PsycINFO, Cochrane library and Web of Knowledge for publications from 2000 to 2013, and revisited in 2015. In addition the work of key authors in the area and reference chaining were used. In order to ensure all relevant studies were identified, broad search terms were used and included: “doctor patient communication”, “patient information needs,” “information seeking”, “shared decision making,” “decision making preferences”, “patient participation”, “oncology”, “cancer”, “quality of life”, “psycho-social needs”, “support care needs”. Specific search terms for colorectal and high grade glioma cancer were used including: “colorectal”, “colon”, “rectal”, “bowel”, “Glioma”, “High grade glioma”, “Glioblastoma”, “GBM”, “Malignant brain tumour” and “primary brain tumour”. Articles were screened for relevance using the title, abstract and finally full paper review.

The literature is presented here using a structure that follows the pathway of a person being diagnosed with, and navigating the treatment decisions to be made when living with cancer.

## **2.2. Colorectal Cancer (CRC): disease incidence, staging and prognosis**

In Europe, colorectal cancer (CRC) was the second most common cancer (447,000, 13%) and the second highest cause of death from cancer during 2012 (215,000, 12.2%) (Ferlay et al., 2015). The incidence rates of CRC are slightly higher in men (13.2%) than women (12.7%) when calculated as a distribution of expected deaths for the five most common cancers (Ferlay et al., 2015). A diagnosis of CRC is strongly associated with age; 80% of CRC occurs in those aged 60 and over, and the median age of diagnosis is 70 (Babb, Brock, Kirby & Jones, 2001). Scotland, the setting for this study, has one of the highest incidences of CRC in the world (43.6 per 100,000 in men, 28.4 per 100,000 in women), with CRC identified as the second most common cause of cancer death (Scottish Intercollegiate Guidelines, SIGN, 2015).

The grading of severity of CRC is based on the TNM staging system (Weitz et al., 2005). This staging system describes the size of the primary tumour (T), any lymph nodes involvement (N), and whether the cancer has spread to other parts of the body, known as metastasis (M). Colorectal cancers are then grouped into stages 1-4; the higher the diagnostic stage, the greater the chance the cancer will be more aggressive. In daily practice and clinical guidelines, the TNM category guides treatment strategies and so the staging system has considerable and direct impact on the treatment a patient receives (Galon et al., 2014). The higher the diagnostic stage of CRC the higher the chance of morbidity within five years of diagnosis (Sobin & Wittekind, 2002).

Treatment is highly effective for early stage CRCs, demonstrating five year survival rates of over 90% for stage I and 72% for stage II disease, reducing to below 60% from stage III onward, with the presence of lymph node involvement and metastasis (Siegel et al., 2013). Metastases are present in 20% of individuals at the time of initial diagnosis and in patients with initially localised CRC, and will develop in approximately 30% of this group within five years (Markowitz, Dawson, Willis & Willson, 2002).

It has been argued that the current TNM classification provides limited prognostic information and does not predict response to therapy (Galon et al., 2014). This argument is based on the premise that clinical outcomes vary significantly among patients classified within the same stage, for example, some patients with advanced-stage cancer can remain stable for years (Mlecnik et al., 2014). Consequently, treatment decisions and predicting prognosis can be difficult for doctors and provide uncertainty for patients.

### **2.2.1. CRC Treatment**

Surgery to remove the tumour and any involved tissue is first line treatment for 80% of patients with CRC: this is accompanied by the possibility of a temporary or permanent stoma (SIGN, 2015). For all Stage I and the majority of Stage II patients, surgery is the only form of treatment. No further oncology intervention is required (SIGN, 2015). Whilst this surgery may be common place, recovering from surgery involves adapting to many different physical symptoms and this can be challenging for patients. In a qualitative exploration of follow up care after surgery in the United Kingdom (UK), Beaver et al., (2010) interviewed 27 patients who reported not knowing whether the physical post-operative symptoms experienced were ‘normal.’



Treatment for patients with Stage I and II CRC is complete following surgery. All Stage III and IV CRC patients are considered for adjuvant chemotherapy as evidence suggests for patients under 75 years of age, this form of treatment improves survival (SIGN, 2015). With surgery and chemotherapy there is a five year survival rate of 77.6% for Stage III CRC patients (Haller et al., 2011) and, for metastatic patients, a 55% survival rate with a median survival rate of 19.5 months (Cassidy et al., 2008). The evidence for providing adjuvant chemotherapy for Stage II patients is inconclusive (SIGN, 2015). Consequently, decisions about the use of chemotherapy for this stage of CRC are based upon consideration of competing risks i.e. risk of treatment-related morbidity versus risk of recurrence and mortality associated with increasing age and comorbidities (SIGN, 2015). Patient preference is often, therefore, a key part of such a treatment decision. The impact of this disease and the potential severity of side effects, indicates that decision support may be beneficial for patients.

Chemotherapy regimes for CRC usually involve a combination of the drugs Oxaliplatin and Capecitabine, administered over a three week cycle for eight cycles over six months. A cycle consists of a two hour infusion of Oxaliplatin on day one, plus one oral Capecitabine tablet twice daily for 14 days, followed by a seven day rest period (Haller et al., 2011). Recent research show a high risk of hospital admission for CRC patients with this form of chemotherapy (Brindle et al., 2012), mainly from gastrointestinal disturbances as a result of which 40% of patients do not receive further chemotherapy. The decision to discontinue chemotherapy before completion is a decision based on the severity of side effects due to the toxicity, in the context of the tumour stage (Brindle et al., 2012). If peripheral neuropathy occurs, then Oxaliplatin can be stopped and Capecitabine continued (Haller et al., 2011). On

completion of adjuvant chemotherapy, patient and tumour response is assessed for patients with residual disease, second line chemotherapy is considered (Haller et al., 2011).

### **2.2.2. Support needs of people with CRC**

As with any cancer diagnosis those diagnosed with CRC face many physical, emotional and existential challenges and concerns. These result from the treatment, concern for whether the treatment will work, and for the impact that cancer may have on the patient's life. It is therefore important to understand the concerns of patients with CRC.

People with CRC tend to demonstrate a similar pattern to their emotional response during their cancer journey. Studies have demonstrated that men and women generally react similarly in response to receiving the diagnosis of CRC (McGaughan, Prue, Paradoo, McIlfatrick & McKenna, 2010). In this qualitative study, all patients reported shock upon diagnosis, although men suggested they were not emotionally impacted by their diagnosis. Following surgery, all participants reported altered bowel habits and felt socially limited if a stoma bag was required (McGaughan et al., 2010). The theme of embarrassment is prevalent in many studies with people with CRC, as CRC symptoms and treatment necessitates detailed discussion about bowel habits and bodily functions. Participants (n=8) in Taylor's (2001) hermeneutical phenomenology study described feelings of isolation and social embarrassment when living with a diagnosis of CRC. Many described feeling unable to communicate concerns for fear of upsetting others, and were aware that the diagnosis impacted on the whole family. Taylor (2001) suggests these findings may be a feature of the existing taboo around discussing bowels, claiming bowels are not discussed in polite company, being associated with dirt and smell. This social isolation further compounds how information about CRC can be sourced and discussed.

Chemotherapy treatment for CRC can be anxiety provoking for patients, specifically regarding its efficacy, the side effects and the possibility of needing to discontinue treatment (Beusterien, Tsay, Gholizadeh, & Su, 2013). Beusterien, et al. (2013) used content analysis to examine 1522 posts from 264 individuals on the most active colorectal cancer web forums that focussed on the experience of chemotherapy. The four most frequently reported chemotherapy side effects cited by patients on web forums included gastrointestinal issues (diarrhoea, nausea, vomiting), skin problems (rash, itch, dryness), neuropathy, and mouth problems (Beusterien, et al., 2013). However, these comments were made by a sample with advanced stage CRC (Beusterien, et al., 2013).

In addition to the most frequently reported side effects, the authors explored the emotional impact of chemotherapy for CRC. Hope was reported as the most frequently stated emotion, followed by anxiety related to treatment efficacy. Hope was represented through gratitude for treatment; “Honestly, if it gave me a 1% higher chance of survival rate then I would have done it” (Beusterien, et al., 2013, p361). This extract represents high levels of expectation of chemotherapy and, considering the often severe side effects chemotherapy can induce, is indicative of existential fear of death. This finding is supported by a systematic review of CRC patient preferences (Currie et al., 2015). Currie et al. (2015) found CRC patients judged a moderate survival benefit to be sufficient to make chemotherapy worthwhile, in spite of significant treatment side effects. The gain of a small potential increase in life expectancy and survival overcame concerns about side effect experience. In contrast patients were prepared to trade reduction in life expectancy over complications from surgery (Currie et al., 2015). These reports suggest people are more hopeful about chemotherapy treatment than they are anxious about its side effects (Beusterien, et al., 2013). Whilst fear of mortality was not

explored in either study, the findings emphasise the need to provide patients with clear and accurate information in order that decisions about treatment are contextualised.

Perceptions about quality of life during and following treatment is a further area of concern for people with CRC. Analysis of 20 interviews with CRC patients, showed that health-related quality of life (HrQoL) is dependent upon 3 key themes: physical experiences, emotional experiences and patient expectations (Wilson, Birks & Alexander, 2010). Key to shaping these three areas was the information given to patients and how this was assimilated by patients. Information was seen as reassuring by allaying uncertainties; however too much information was perceived to provoke anxiety (Wilson et al., 2010). When participants did not receive enough information they reported feeling unprepared for treatment or retrospectively regretful of treatment decisions (Wilson et al., 2010). Unfortunately, it is unclear at what time point following surgery the interviews took place which limits the impact of these findings.

Emotional distress is seen as an inherent part of a cancer diagnosis. In a cross sectional survey of 128 CRC patients, 19% of the sample were found to be highly anxious [using the Hospital Anxiety and Depression scale] and 14% were highly depressed [using the Centre for Epidemiological Studies Depression scale] (Simon, Thompson, Flashman & Wardle 2009). This survey found those with advanced disease stage (3c and 4) reported poorer quality of life, more anxiety and depression, and were less satisfied with medical interactions. Furthermore, participants with lower socioeconomic status reported high anxiety, depression and the least satisfaction with medical staff interactions. Although the results should be interpreted with caution due to a small sample size and lack of sample profile, there is clinical impact of this study. Patients with CRC may be experiencing anxiety and depression and this

can impact on their satisfaction with health care, with patients requiring decision and treatment support as their cancer journey progresses.

### **2.2.3. Improving CRC support through information**

As briefly outlined in Chapter 1, there have been strong national guidance recommending that information sharing with patients is a key component of patient-centered care, especially within cancer care (NICE, 2011). The NICE guideline for people with CRC recommends that patients are offered information about all treatment options available (including no treatment) alongside the risks, benefits and side effects before treatment is initiated. It is suggested this information should be clear and free from jargon, and used alongside clinician-endorsed support group organisations information (NICE, 2011). Additionally, guidance indicates treatment decisions should be made following informed discussions between the patient and doctor. The Scottish Intercollegiate Guidelines (SIGN, 2015) on managing CRC recommends some additional best practice guidance including the suggestion that provision of information should be appropriate to the preference of the patient and that communication should be sensitive, understandable and accurate. Furthermore, use of summaries or recordings of consultations is encouraged. The SIGN guidance, compared to NICE guidance, provides a more directive strategy for clinicians, leaving less room for the subjective interpretation of recommendations.

In cancer services, information is often used to address areas of uncertainty and concern, and specifically help to regulate emotional distress (Wilson et al., 2010). Uncertainty about treatment options is prevalent in the experience of CRC and it has been conjectured that the role of uncertainty in CRC alongside other cancers may influence the patient's experience of cancer (Shaha et al., 2008). Knowles et al. (1999) in a study conducted with CRC patients,

found uncertainty was present at critical times in the patient's journey: at diagnosis, before knowing if chemotherapy was needed, and at the end of treatment. In order to manage uncertainty, many patients engage in information seeking behaviours (Shaha et al., 2008).

In 1999 Beaver, Bogg & Luker, used the Information Needs Questionnaire (n=42) to identify the top three priority information needs of people with CRC and compared these with people who had breast cancer. The top three information needs were; likelihood of cure, spread of disease and treatment options. The same three items were also rated top three by breast cancer patients; suggesting these areas of information may not be cancer specific. In a more recent large scoping review of the literature (239), the top three information needs were: treatment related information with a focus on treatment side effects, rehabilitation information with a focus on stoma care, and information about coping with a focus on emotional support (Van Mossel et al., 2012). As the two studies were conducted thirteen years apart, this finding may suggest an evidence-based social rejection of cancer as a death sentence, and the acceptance of cancer as a disease from which one may survive.

With regards to information sources, Nagler et al. (2010) undertook a large (n=2010) postal survey in Pennsylvania to explore differences in information seeking amongst breast (n=678), prostate (n=651) and colorectal cancer patients (n=681). The most frequently cited source of information was doctors (Nagler et al., 2010), a finding supported by van Mossel et al.'s review of the literatures (2012). Interestingly, early stage CRC patients were reported to be less likely to search for information than people with breast or prostate cancer (Nagler et al., 2010). The authors hypothesise this may be attributable to a lack of treatment options provided to patients in what is often framed as a straightforward pathway of care.

Although both studies report doctors as the main source of information, patients also seek to make sense and understand their situation through comparison and conversation with other cancer patients (McGaughan et al., 2011). In an interview study (n=38), cancer patients reported how they sought information from other cancer patients about prognosis, treatment, (especially chemotherapy to provide information of the many different types and subsequent side effects), and coping strategies (McGaughan et al., 2011). Some patients became confused with the many different perspectives and conflicting information shared, whilst others were able to select relevant information and apply this to their own situation. In raising the issue of gathering information from multiple sources, this study highlights the amount of information patients are exposed to, and that whilst knowledge from other patients can be useful to provide insight, it can also be confusing. This emphasises health care professionals' role in helping patients make sense of information (Beaver et al., 2010). This helps the patient to regain control in their life, further reducing patient anxiety and fear (Lithner, Klefsgard, Johansson & Andersson, 2015).

The need for information in people with CRC is present across the CRC population, and, as shown by a Scottish survey (n=80), across all demographic variables including age, sex, education status or marital status (Knowles et al., 1999). In the same study information at the pre-treatment stage provided reassurance, unless it held unexpected messages such as no guarantees that chemotherapy would improve survival. This is supported by studies reported earlier in this chapter (e.g. Beusterien, et al., 2013, Wilson et al., 2010). Information was valued and assisted people with coping at the time of diagnosis (Knowles et al., 1999). However, some patients reported difficulties in making sense of information about chemotherapy. They reported that clinicians took time to explain yet participants remained overloaded or confused (Knowles et al., 1999). This confusion was often present when

clinical descriptions did not meet patients' expectations on the information needed (Knowles et al., 1999). Just under half of participants experienced difficulty with decision making with clinicians due to a lack of understanding, responsibility, and no definitive clinical suggestion. Although this is an old study, it highlights key points about the delivery and assimilation of information, and its' impact on decision making.

#### **2.2.4. Decision making in CRC**

Information for CRC patients is also used to make treatment decisions. The body of work by Beaver et al., in 1999, 2005, 2007 and 2009 has substantially added to the empirical understanding of CRC patient's decision making preferences. This work was all undertaken in the North West of England so has useful and relevant implications for this thesis. One of the first studies to explore the decision-making needs of CRC patients was undertaken by Beaver, Bogg & Luker (1999) by drawing comparisons with the decision-making needs of breast cancer patients. Results demonstrated that 78.3% (n=36) of CRC patients stated they preferred the doctor to make treatment decisions, compared to 52% (n=78) of breast cancer patients. In this early study, CRC patients reported they took a passive role in decision making (80%, n=36/45) and for the majority, (60% n=27/45) this had been their preference (Beaver et al., 1999). When compared with breast cancer patients, it was unclear why CRC patients wanted to remain passive in decisions. However, the sample size of this study was small, conducted across the treatment pathway and with only one consultant.

The authors explored this passive decision-making role preference in a larger (n=41) qualitative study cohort (Beaver et al., 2005). The CRC patients in this study were involved in decision making in the medical consultation process and were frequently provided with information across treatment stages (Beaver et al., 2005). In the previous study decision



making had been defined as deciding the treatment outcome, and not involvement in the decision-making process which highlights the importance of using clear operational definitions of terms in empirical work. The study reported that patients wanted to be involved in the decision-making process, but did not want to take responsibility for the decision.

In continuing their research programme, Beaver et al. (2007) undertook research to explore the potential for shared decision making (SDM) from the CRC health care professionals' perspective (n=35 interviews, including doctors, nurses and allied health professionals) (Beaver et al., 2007). Findings suggest that health care professionals acknowledged and favoured SDM, but in reality their behaviour towards this was tempered by different CRC patient preferences towards information sharing and decision making in the medical consultation and the complex nature of the information to be shared (Beaver et al., 2007). In order to quantify patient preference, Beaver et al., (2009) used the 2005 and 2007 findings to design an attitudes rating scale to explore CRC participants attitudes towards involvement in decision making. They concluded the majority of participants (94.7%) wanted to know what was happening and be involved in decision making, although only 51.7% actually wanted to decide. This provided further support for the authors conclusion based on the 2005 findings that CRC participants wanted to be involved in the process but not necessarily the outcome of decision making.

In contrast to the studies by Beaver et al. (1999, 2005, 2009), a recent large scale survey in the U.S.A. reported that in a sample (n=5315) of CRC patients (56%) and lung cancer patients (45%), only 6% of patients preferred clinician-controlled decisions, whilst 58% preferred a shared decision making role (Kehl et al., 2015). As decision making preference

was measured using an instrument similar to the one used by Beaver et al., (1999), this may reflect a change in social attitudes with an acceptance and uptake of involvement in decision making.

It is clear that despite evidence indicating a shift towards greater uptake of SDM, certain treatment decisions remain autonomously made by medical staff. For example, in a recent audit of decision making in CRC multi-disciplinary team meetings (n=316 CRC patients, median age 68.3), age was found to significantly impact the likelihood of withholding chemotherapy for CRC patients (Hamaker et al., 2015) with those over 70 years of age significantly less likely to be offered chemotherapy (Hamaker et al., 2015). The large U.S.A. survey described above reported that both CRC and lung cancer patients rated the quality of their care and the clinician's communication skills as lower when they experienced clinician controlled decision making (Kehl et al., 2015). This association between clinician controlled decision making and lower rating of care quality was present regardless of the patient's decision-making role preference (Kehl et al., 2015). This suggests that where clinicians do not control the decision-making process, the patient perceives the care received as higher quality of care, regardless of the patient's preferred decision-making role. Interestingly, this finding is supported by an earlier small scale survey (n=220) of CRC patients in Australia which reported trust in the clinician as the most significant factor within the treatment decision process (Salkeld, Solomon, Short, & Butow, 2003). Trust, defined as competency, openness, clarity of language and listening skills, appeared crucial for the patient to accept the decision made (Salkeld et al., 2003) and are aspects of care central to the implementation of SDM.

It is clear that understanding of information needs and shared decision making has evolved over time, and remains a complex area. Perhaps one of the biggest challenges in this area is that although published protocols exist detailing conceptual models of shared decision making per se, no model of shared decision making specific to CRC exists (Leon-Carlyle et al., 2009). This lack of consensus makes academic enquiry and critique and clinical application difficult.

#### **2.2.5. CRC: Summary**

CRC is one of the more common types of cancer and impacts a relatively large proportion of those with cancer in the Scottish population. Although guidelines for treatment exist, consensus is still developing about the predictive capabilities of the staging systems and the value of adjuvant treatment for Stage II patients. CRC patients are concerned about the side effects of treatment and embarrassment resultant from the nature and disease management of bowel cancer. Information can alleviate patient concern and help people to cope. Although health care policy recommends the involvement of cancer patients in decision making, the extent to which this occurs in practice is unclear. Furthermore, it is unclear whether people with CRC wish to take an active or passive role in decision making about their disease. However, involvement in the process of treatment decision making appears important in light of significant treatment side effects and the impact of CRC on the patient's life.

### **2.3. High Grade Glioma (HGG): Disease Incidence, Staging and Prognosis**

Primary brain tumours account for just 2% of all cancers diagnosed in adults in the UK (Mirimanoff, Gorlia & Mason, 2006). In the UK, only 4,987 people were diagnosed with a primary brain tumour in 2009 in comparison with 40,000 women diagnosed with breast cancer and 25,000 men diagnosed with prostate cancer (2009, CRUK). With the annual incidence rate of primary brain tumours being 7 in 100,000 (McKinney, 2004) primary brain tumours are relatively rare. However, the prognosis for this group is extremely poor (Wang & Jiang, 2013). The most common primary brain tumour in adults, and comprising 87% of those diagnosed are High Grade Gliomas (Grade 3 and 4) or HGG. The majority of these are identified as glioblastomas (Guilfoyle, Weerakkody, Oswal et al., 2011).

Although HGG affects adults of all ages, the incidence of this tumour rises after the age of 30 years, with a diagnosis of HGG most commonly made in those 65 and over (Chakrabarti et al., 2005). A reduced incidence rate has been observed for those aged over 75 years, although this may be due to less investigation in elderly patients where symptoms could be attributed to other comorbid conditions e.g. stroke (McKinney, 2004). Primary brain tumours also demonstrate gender disproportion, with males more likely to be diagnosed than women with a ratio of 1.5:1 (McKinney, 2004).

HGG is an incurable disease and less than 5% of patients survive 5 years from diagnosis (Shaw et al., 2004). Despite intensive biological research, prognosis has not improved significantly over the last decade. Survival, and its quality, is dependent on age at diagnosis, pathology, grade of tumour and presenting symptoms (McKinney et al., 2004). Elderly patients (Mirimanoff et al., 2006) or those with poor performance status (Keime-Guibert et al., 2007) tend to have the worst prognosis. Current median life expectancy with optimal

treatment is 12 to 14 months (Stupp et al., 2005), though few patients survive 3-4 years from diagnosis (Catt, et al., 2008). Although HGG is rare, HGG is the third leading cause of cancer related death among men aged 15-54, and the fourth leading cause of cancer related death for women aged 15-34 (Kesari & Stiles, 2006). Reflecting on these statistics in a different way, the average years of life lost (AYLL) for cancer patients is 12.5 years, brain cancer patients suffer the highest AYLL at just over 20 years (Burnett et al., 2005).

### **2.3.1. HGG Treatment**

Following initial presentation with symptoms of a brain tumour, treatment is often initiated rapidly; the intent of treatment is palliative. Clinical management of HGG often depends on the extent of the tumour mass, but those diagnosed will frequently undergo surgery, radiotherapy and chemotherapy before dying from their disease (Guilfoyle et al., 2011). Owing to the infiltrative growth of HGG, a relapse is inevitable (Salander 2009).

Surgery to excise the tumour is the first therapeutic modality for most patients but a complete resection of high grade tumours is not possible. Radiotherapy and chemotherapy are then subsequent forms of therapy (Salander, 2009). Despite improved technologies, effective therapies for substantially improving life expectancy remain elusive (Keime-Guibert et al., 2007). Radiotherapy has been the principle adjuvant modality since the late 1970's, with the addition of chemotherapy demonstrating only modest benefit until recently (Stupp et al., 2005). The introduction of radiotherapy and combined chemotherapy has improved the prognosis for some HGG patients, particularly in younger patients who are otherwise fit and well (Mirimanoff et al., 2006). As commented by Guilfoyle et al. (2011), there is a clear need for more effective therapeutic interventions.

Current treatments therefore can only extend survival, not provide a cure. In some centres, and for some patients, doctors may perceive treatment to be unwarranted due to the adverse effects of treatment further diminishing the patient's quality of life (Davies, 1996). However, many patients who respond to treatment experience temporary improvement in their symptoms (Catt et al., 2008).

After initial diagnosis, primary treatment will continue for six to twelve months. After this, patients will only return to hospital when initial symptoms begin to re-present, signifying a re-growth of the tumour. Treatment options at this time are often significantly less active, attending more to symptom control. If patients survive to this point, their needs start to diversify depending on their abilities as they return to daily activities (Janda et al., 2006).

### **2.3.2. Support needs of people with HGG**

Following initial presentation with symptoms, treatment is rapid with patients admitted for surgery as emergencies or electively as urgent cases (Guilfoyle et al., 2011). This has several care challenges. When taken into surgery as an emergency, the time available for pre-operative counselling and exploration of the impact of a diagnosis of HGG is diminished. After surgery confirmation of a diagnosis is not possible until pathology results have been returned. This period of time is critical as patients and relatives responses and experiences of the time period before formal diagnosis is predictive of future adaptation to illness (Weisman & Worden, 1977). However, few studies have explored this time point with regards to HGG.

Three qualitative studies that have undertaken research in this area are Salander, Bergenheim, Hamberg and Henriksson, (1999); Halkett Lobb, Oldham and Nowak (2010) and Cavers et al., (2012, 2013). Salander et al., (1999) interviewed 28 patients diagnosed with HGG

retrospectively about their experiences of symptom onset to the moment of diagnosis. Using thematic analysis, the ‘trigger symptoms’ were described as headache, seizure, motor/sensorial dysfunction and mental dysfunction, and barriers to seeking help included the patient normalizing symptoms or avoiding them. A passive role by a spouse further mitigated help seeking. Such delay in seeking assistance supports the earlier work of McKeran & Thomas (1980) who reported that time from first symptom to diagnosis was nine and a half months. Later work by Salander et al., (1999) found this time period to be six months.

Halkett et al., (2010) interviewed 19 people diagnosed with a HGG about their information and support needs, utilising purposive sampling to capture a range of stages in the disease process (during treatment, at disease recurrence). Using a grounded theory approach, the authors’ report that the time period after surgery was particularly uncertain due to the time needed for pathology results to confirm a diagnosis. Patients reported this waiting period as difficult and wanted additional information to be provided. It should be noted that interviews were conducted retrospectively and therefore were based on recollection of experiences. There is also suggestion that surgeons preoperatively reassure patients and families that information about the outcome of surgery will be available immediately, while the reality is that this is impossible (Lobb, Halkett & Nowak, 2011).

As part of a larger exploratory serial interview study with HGG patients (n=26), Cavers et al., (2013) conducted 13 patient interviews (n=10 jointly with a relative) prior to a confirmed diagnosis of HGG. These were conducted either immediately before surgery or in the week after but before diagnosis. Utilising a grounded theory approach, findings identify a high level of emotional distress and immense uncertainty about the future at this time. This time period was described as being ‘in limbo’, characterized by anguish and speculation about the

unknown. Drawing on the same data Cavers et al. (2012) mapped the physical, social, psychological and existential trajectories from diagnosis through to post-treatment for people diagnosed with HGG. The physical trajectory began, as in the Salander et al. study (1999), when patients presented with varied problems from a sudden isolated seizure to more gradual symptoms including headaches and nausea. The social trajectory illustrated substantial disruption immediately post-surgery at the same time as a reduction in psychological wellbeing. Following surgery, anxiety was at its most acute, and the sense of uncertainty at its peak with caregivers feeling great stress during this time. Existential distress was noted pre-diagnosis of HGG when some participants could not find a sense of meaning in their lives. Some participants became more spiritually aware whilst others turned to friends, family and professionals for support. Whilst waiting for confirmation of their diagnosis, participants reported seeking procedural information about what would happen next in order to compensate for the lack of information about investigation tests (Cavers, 2012). This challenging time following surgery and whilst waiting for a diagnosis is reflective of experiences in the general cancer population where the period from the first suspicion of cancer to the confirmation of the disease is described as a period of great stress (Sægrov & Halding, 2004). One common theme running through all this empirical work is the need for patients to have more information.

What is clearly highlighted in the literature is that living with a life limiting diagnosis such as HGG, is characterised by profound distress and anxiety. One survey with 52 primary brain tumour patients in the UK (Keir et al., 2009) demonstrated that high reporting of emotional concerns correlated with increased distress scores. When compared to the general cancer population, Keir et al. (2009) reported that this population reported significantly more concerns. On this basis it is suggested that those diagnosed with a primary brain tumour



experience more intense and enduring distress. In a systematic review it was shown this distress extends to other family members and the patient's support network (Sterckx et al., 2012).

Living with on-going physical symptoms such as memory loss and communication problems only served to add to some patient's distress and frustration (Keir et al., 2009), with patients describing how their initial reaction of coping with HGG and holding onto life, later turns to more realistic awareness of the inevitability of death (Molassiotis et al., 2010). However, for others, coping with a HGG diagnosis has been associated with a positive reappraisal and redefinition of life (Strang & Strang, 2001). This often occurs as a result of the existential reflection that occurs in patients during their HGG cancer experience. However, the ability of health care staff to support patients in discussions about these areas has been questioned with patients perceiving staff to be too busy, stressed, afraid or unskilled in this area (Adelbratt & Strang 2000; Strang & Strang, 2001).

### **2.3.3. Improving HGG support through information**

Evidence-based and clinical guidelines to inform information sharing with patients recommends that communication with patients with primary brain tumours and their families should include discussion of diagnosis, prognosis, treatment options, recurrence and end of life care (NICE, 2006) and that clinicians should inform patients of the type of information available, elicit how much information a patient wishes to receive and then individualise the information to the patient's need (Halkett et al., 2010). The importance of revisiting this discussion at multiple time points, rather than believe this to be a one-off communication episode is also well recognised (Clayton, 2008).

Whilst this may appear relatively straight forward to achieve, it is clear that information sharing with HGG patients is complex. In a study by Lobb et al. (2011), single interviews were conducted with HGG patients (n=19) and their caregivers (n=21) within one year of diagnosis. All interviewees described their shock and disbelief at being given the diagnosis. They also reported that following diagnosis, they found it difficult to absorb and make sense of prognostic information. Many could not recall the details of the diagnosis or prognosis, or they believed they had not been given complete information. These issues are supported by Halkett et al.'s work (2010) who found patients valued the presence of a caregiver in consultation to minimise the burden of recall. All spoke of the need for hope and reassurance and the fact that hope was often taken away on receiving the prognostic information. Reassurance by health care staff that participants would not be abandoned, and that everything possible would be done, motivated patients to continue with treatments. Lobb et al. (2011) noted that patients often coped with the distressing prognostic information by rationalising that average life expectancy statistics did not apply in their case. Caregivers in particular did not believe doctors could predict individual survival and preferred to stay positive. Participants wanted clinicians to be more compassionate and empathic, and include some positive messages in their delivery of such bad news.

HGG patient's value detailed information about illness, symptoms and the future (Salander & Spetz, 2000). Through serial interviews throughout the course of their disease HGG patients (n=25) reported they required concrete information about treatment schedules, future appointments and the practicalities of dealing with everyday life (Salander & Spetz, 2000). In their study Salander & Spetz (2002) found patients expressed satisfaction with information but posed few questions about prognosis and were satisfied with simply knowing their diagnosis and treatment regimen. The authors concluded many chose not to voice the 'vital

questions' about the future, choosing instead to ask more ordinary ones about treatment. In the early stages of coming to terms with a diagnosis of cancer, Cavers et al. (2012) report participants were torn between wanting clear, direct and honest information and being unsure if they could assimilate and cope with the impact of information about their diseases (Cavers et al., 2012). However, in contrast other studies report how information helps participants to cope with the uncertainty inherent in this disease (Janda et al., 2006, Catt et al., 2008, Cavers et al., 2012). This highlights the paradox of collective patient need as portrayed by the literature contrasted with the individual and subjective informational needs of each unique individual person with cancer.

In one of the few quantitative studies reporting the information needs of HGG patients (Diaz, et al., 2009) twenty-six patients reported their information preferences: 50% wanted all possible information, 23% wanted only important aspects, and 27% wanted only critical aspects. Fifteen percent of patients expressed a wish to ask their HCPs more questions. Younger patients (aged 65 years) wanted more information than older patients. Anxiety was found to be lower in patients who wanted to know everything about their illness, understood the information better, and were more satisfied with the information that they received. This is supported by Cavers et al., (2012) who reported that having appropriate information reduced anxiety for many people.

Differences in information preferences may be partly explained by the individual appraisal of the need for information. Patients often fluctuate between wanting to know and not wanting to know (Halkett et al., 2010). Interviews with carers (n=21) suggest this shift in need often corresponds to the unique illness trajectory and rapid shifts in disease status (McConingley, Halkett, Lobb & Nowak, 2010). Rosenblaum et al. (2009) in their reflections about providing

care to patients, note that patients often prefer information adapted to suit their needs and at the same time wanted to urgently know what their treatment plan would be. Conversely Lepola et al. (2001) interviewed patients pre and post-surgery (n=8) found patients report the feeling of urge and haste in making treatment decisions should be decreased. Timing of information was also felt to be an issue as often patients were not ready to absorb information or discuss prognosis (Halkett et al., 2010).

Qualitative findings from a longitudinal interview study with 17 patients found higher information needs and anxiety were reported prior to commencing treatment, significantly decreasing after treatment begins (Halkett et al., 2012). They identified four time points as critical for information needs; the first consultation, the planning appointment, the first day of treatment and approaching treatment conclusion (Halkett et al., 2012). Patients were found to appreciate the opportunity to ask questions of medical staff in order to prepare for the future (Halkett et al., 2012). Through serial interviews over the course of the disease process Janda et al. (2006) found patients wanted continued communication by healthcare professionals about their prognosis throughout the course of treatment and beyond. Without this, patients and partners described being unable to discuss the severity of the situation openly together (Salander & Spetz, 2002).

Communicating bad news is demanding and a significant source of stress for clinicians, patients and caregivers (Ptacek & McIntosh, 2009). A review of the literature between 2000 and 2007 revealed that no studies clearly identified what best practice is in breaking the bad news of HGG or discussing poor prognosis (Catt et al., 2008); this highlights the challenge clinicians face. Clinicians seek to strike the difficult balance between truth telling, preparation for dying, and providing positivity (Ford, Catt, Chalmers & Fallowfield, 2012).

What can be concluded is the need for clinicians to be competent in communicating bad news, receiving appropriate training in order for these skills to be practiced (Ptacek & McIntosh, 2009), and for any information sharing to be customized in the way it is provided (Halkett et al., 2010). Written information at the time of discharge following surgery has been reported as one particularly helpful resource to improve recall of information (Paul, Hendry & Cabrelli, 2004).

The value of written information as a record has been qualitatively explored in a study with high and low grade brain tumour patients and caregivers by Janda et al. (2006). Data were collected in focus groups (patients n=12, caregivers n=10) and telephone interviews (patients n=6, caregivers n=8). Participants reported high need for both verbal and written information at the time of diagnosis in order to make sense of their situation and enable understanding of HGG, its treatment and side effects. This research is supported by a review of the literature (Catt et al., 2008). Janda et al. (2006) call for further research to develop strategies to meet on-going unmet information needs in patients and caregivers.

Molassotis (2010) in their small (n=9) serial interview study found that patients needed better information, particularly preparatory information on what to expect throughout the course of their disease, as well as regular assessment of their understanding. Good quality information was found to raise awareness of available services and enable carers to advocate effectively for the patient and support important treatment decisions (McConingley et al., 2010). Often carers were noted to have a higher need for information than the patient (Salander and Spetz 2002). Interestingly, a 2008 literature review found patient's satisfaction with information was often greater than that of their spouse (Catt et al., 2008). Participants in Janda et al.'s (2006) interviews suggested proactive dissemination of information could minimise and

relieve pressure for patients and carers alike (2006) whilst Halkett et al., (2011) called for information to be tailored to the individual receiver.

Two literature reviews have been undertaken to examine the literature concerning the experience of living with HGG and the resultant information and support care needs (Catt et al., 2008; Davies & Higgingson, 2003). The first review examined literature up to 2000 (Davies & Higgingson 2003) whilst the second reviewed literature from 2000 – 2007 (Catt et al., 2008) Both reviews conclude more research is needed to assess supportive interventions to attend to patients unmet information needs and educate staff with regards to caring for this population of patients.

#### **2.3.4. Decision making in HGG**

In addition to threatening life, HGG threatens mobility, cognition, perception and emotion (Salander, 2009). Unlike patients from other cancer populations, HGG patients are more likely to suffer with physical and cognitive impairments (Halkett, 2010). Patients often present with features including cognitive decline, headaches, seizures and motor deficits (Deangelis, 2001) which are often lasting, raising the need for decision making capacity to be assessed and reviewed.

Medical decision-making capacity is relevant for patients with HGG as there are ongoing and challenging medical decisions to be made whilst coping with a disease that rapidly erodes cognition (Ford et al., 2012). The issue of capacity and personal autonomy can be a sensitive area for patients when, due to risk of seizure and cognitive deficits, they require 24 hour supervision (Pelletier 2002): this occurs whilst attempting to maintain independence where possible (Sterckx et al., 2012). However, in balancing these demands, this often resulting in

the humiliating process of patients no longer being recognised as a complete person (Strang & Strang 2010) with carers becoming overprotective (Sterckx et al., 2012).

Against this backdrop, the importance of enabling patients to be involved in decision making, whilst capacity exists, is important. This was explored in an early qualitative study conducted in the UK (Davies, Clarke & Hopkins, 1996). Seventy five patients and sixty-six caregivers were interviewed within three months of HGG diagnosis to understand patient and carers' experiences of diagnosis and prognosis. Whilst the majority of patients (71/75) understood they had a brain tumour, three levels of awareness about the prognosis were identified. A quarter of patients were fully aware of their prognosis, characterised by recognition of little chance of cure and expressing thoughts and fears about dying. Less than one third of patients were categorised as partially aware of their prognosis expressing some fear of dying whilst anticipating a reasonable chance of cure. Overwhelmingly 43% (24/75) conveyed no awareness of prognosis and the outcome of death although relatives in the study were three times more likely than the patient to be aware of the prognosis (67% vs 21%). Although this study was conducted in 1996, it highlights important features about patient's understanding of their disease and the impact on their decision making.

In considering how decision making can be improved, Janda et al.'s survey (2006) gives us some options. In their work they used a survey with 75 brain tumour patients to explore unmet supportive care needs. Specific areas highlighted by patients where more support and understanding was required included: coping with the physical side effects of the tumour and treatment and changes in mental thinking or ability, feeling like a different person before the brain tumour, information on the latest developments in research and treatment in brain tumours, and coping with changes in abilities to work. With regards to decision making,

patients identified uncertainty about the future and not having one identified member of staff to talk to as problematic. The prognosis for HGG is certain, but the length of survival is unavoidably uncertain. Uncertainty is shown to obstruct comprehension and increase a sense of chaos and anxiety (Stang & Strang, 2001). This sense of uncertainty often leaves patients feeling frustrated, unclear about what to expect from treatment and the future (Halkett, 2009). Often this can lead to patients feeling out of control and unable to plan their life (Halkett, 2009). As a result uncertainty can lead to difficult doctor-patient communication, as concrete facts about the future and success of treatment are absent. Davies reported that doctors in some medical settings may perceive treatment to be unwarranted as it may diminish quality of life further by the adverse effects of treatment (Davies, 1996). Treatment provides the possibilities of extending life post-surgical morbidity. Although treatment provides the possibility of extending life, side effects such as post-surgical morbidity, effects of radiotherapy on the normal brain, chemotherapy-induced toxicity, high dose steroids and anticonvulsants can all negatively impact quality of life (Remer & Murphy, 2004).

When considering decision making in HGG, many patients in qualitative reports of support care needs (Janda et al., 2006) identify that having an assigned member of staff who can help patients manage their emotions, answer medical questions, and mediate between carer and patient is important. Patients and carers clearly want support in understanding not just technical and medical knowledge, but also someone to listen to their views about care (Catt et al., 2008). Patients with HGG and carers who report having higher needs, consistently expressed greater interest in services that could provide greater support and improve their skills in communicating with doctors in order to have their concerns heard (Janda et al., 2006).



With time to adjust to a diagnosis some people may begin to try to regain an internal locus of control, and this may result in a shift away from their initial willingness to defer decision making to professionals (Shaha et al., 2008). Information seeking is an effective strategy when combined with an internal locus of control and may assist patients to accept cancer as part of everyday life (Ramfelt, Severinsson & Lutzen, 2002). Rutten et al. (2005) in a systematic review of 122 articles found that when the provision of information was adequate and appropriate, it had a powerful impact and could reduce patient's anxieties. Information and knowledge is therefore needed to develop patients cope with unfamiliar situations, such as coping with cancer (Nanton, Docherty, Meystre & Dale 2009).

#### **2.3.5. HGG: Summary**

HGG is a rare disease, but one that holds catastrophic consequences for the patient and their family. With current treatments focussed on palliative rather than curative outcomes, the nature of the information to be exchanged between doctor and patient, and the types of questions raised, require the utmost sensitivity. Despite understanding the information needs of this patient population, and guidance on how to deliver distressing information clearly, and over time, people with HGG continue to report overall dissatisfaction about their communication with health care professionals (Ford et al., 2012).

## **2.4. Support needs of the general cancer population**

The previous sections of this chapter have detailed the experiences and needs of cancer populations specific to this thesis, those being patients with CRC and HGG. In concluding this introductory chapter, a brief discussion is offered on where this sits with regards to what is known about the needs of the wider cancer population.

Research about people diagnosed with cancer consistently reports that the majority of people want and expect to be involved in decision making about their treatment (Davidson & Denger 2002; Coulter & Jenkinson, 2005) with patient involvement in decision known to improve patient understanding, satisfaction and confidence in the treatment decisions made (Edwards & Elwyn, 2006). However, many cancer patients do not achieve the involvement they desire in treatment decisions, often leading to decisional regret (Brehaut et al., 2003). The success of the cancer consultation depends on understanding of the patient's information needs, and the communication skills of both the doctor and the patients to engage in communication that meets these needs.

### **2.4.1. Information needs**

Information needs in the cancer consultation can be defined as 'a recognition that knowledge is inadequate to satisfy a certain goal' (Echlin & Rees, 2002, p.5). In general, patients are interested in receiving information that will help them understand their cancer, relieve uncertainty, make decisions and cope with treatment (Squires et al., 2005). This is challenging for both patient and clinicians when uncertainty features prominently throughout many cancer patients' journeys. With uncertainty defined as the 'inability to determine the meaning of illness related events' (Mischel 1991, p.167), the perceived lack of control over the situation can be anxiety provoking (Gaudine, Sturge-Jacobs, & Kennedy, 2003). Uncertainty can be triggered by a lack of unintelligible information (Shaha et al., 2008) and,

in the general cancer population, there is an unfulfilled need for security and certainty (Halldorsdottir & Hamrin, 1996). Information about cancer treatment can bring certainty and a sense of control for patients.

There is a strong body of evidence reporting that cancer patients wish to know all information (Fallowfield & Jenkins, 2004), although many social, personal, and emotional factors impact on this (Leydon, 2000). In one of the largest UK studies, a sample of 2331 patients of multiple cancers across 34 hospitals in the UK, 87% preferred as much information as possible; information they regarded as “good” and as “bad” (Jenkins, Fallowfield, & Saul, 2001). When reviewing individual item replies for the areas; ‘what the chances of cure are’ and ‘what all the possible treatments are’ just over half of the participants (53.9% and 54.2% respectively) reported these areas as ‘absolute need.’

In contrast, a qualitative study conducted in the UK with 17 cancer patients, within 6 months of receiving a diagnosis of cancer, identified that patients wished to be given only basic information regarding diagnosis and treatment but were content with no more (Leydon et al., 2000). They suggest patients may engage in avoiding information or using silence as a way of maintaining hope (Leydon et al., 2000). This was found to be more common among men who preferred not to ask questions to avoid information about death (Leydon et al, 2000). In this respect, efforts to maintain hope impeded the drive find out further information (Leydon et al, 2000). These patients wished to maintain a ‘life as normal’ stance, putting their trust in the doctor to do all that is necessary (Leydon et al, 2000). In contrast, in a qualitative study with advanced cancer patients, clear communication about prognosis and curability was not found to decrease hope (Smith, Dow, Khatcheressian & Lyckholm, 2010). Hope is an important narrative in the cancer patient’s experience (Leydon et al., 2000). Good clinical practice

requires that clinicians balance information provision to address the uncertain and certain in treatment options, realism and optimism, hope and fear (Leydon, 2008).

Differences in information preferences may be partly explained by the individual appraisal of information from one's current perspective. Faced with a serious illness, information can either be a risk (loss of hope) or a reward (strengthen coping through a sense of knowing) (Wilson, 1977). Understanding the patient's perception of this threat and so their information needs, is key to providing personalised care.

Information seeking has been demonstrated to play a critical role in an individual's efforts to cope with the disruption of quality of life associated with a cancer diagnosis (Arora, Johnson, & Gustafson, et al. 2002). Information seeking is a recognized and often used coping mechanism that increases comprehension and manageability (Strang & Strang 2001). It appears information needs and information seeking behaviour cannot be explained purely by cognitive drives but also by their perceived level of stress and therefore the patient's own coping strategy (Wilson, 1997). This is evident in circumstances when gaps in a patient's knowledge are clear and yet information is not sought (Leydon, 2000).

Wilson (1997) suggests if we assume, for whatever reason, a person experiences an information need, there must be an attendant motive to actually engage in the behaviour of seeking. The stress/coping perspective offers a useful basis for further understanding this behaviour. Folkman (1984) notes that coping has two major functions: "the regulations of emotions or distress (emotion-focused coping) and the management of the problem that is causing the distress (problem focused coping)." In terms of information seeking within

cancer an individual may be looking for the factual information about treatment or information to enable dealing with the problem emotionally (Wilson, 1997).

Bensing and Verhaak (2004) contextualise this stress coping perspective into the medical encounter in their model. They propose patients in general have two needs when they enter the medical consultation with their doctor: a cognitive need; the need to know and understand, and an affective need; the need to feel known and understood. The cognitive need is met by appropriate information provision from doctors to, for example, enable interpretation of symptoms or set expectations about treatment. The affective need is fulfilled through the doctor's supportive behaviour. This need is much more implicit than the cognitive one, often not articulated by the patient, it requires the doctor to elicit concerns through the use of adequate communication skills. If this is completed successfully they propose it can turn the consultation from 'powerful placebo' to a place for 'empowering the patient.' In a large qualitative study of 200 patients (Thorne et al., 2005) the theme of 'being known' emerged prominently. One aspect of this theme was the patient's observations of when clinicians acknowledged them as a unique human being, distinct from their disease.

In exploring literature from the wider cancer population, there are common themes that emerge and resonate with the CRC and HGG population-specific literature. The importance of decision making, the impact of uncertainty and patient coping, and the role of information in bringing a sense of control to cancer patients, is reinforced. This not only adds to what is known about the information needs and experiences of people with CRC and HGG, but further extends our understanding as to the importance of information in medical consultation, and the consequences for patients when these needs are not met.

## **2.5. Conclusion**

This chapter has given a broad overview of the distinct disease trajectories and decision making need of patients with CRC and HGG. In undertaking this, it has detailed the challenges for the two cancer populations that will be the focus of this thesis. Through further understanding gained from research of the general cancer population, the challenges for both populations are contextualised and emphasised. It has been reported that communication could be improved when talking with, and giving information to CRC and HGG patients. Chapter 3 will present a more in-depth explanation of what is known in the literature about medical consultations, information sharing and shared decision making.

## **Chapter 3: Shared decision making - from policy to practice**

### **3.1 Overview**

This chapter will explore current understanding of shared decision making (SDM) in health care, the substantive area that underpins this thesis. To undertake this, the health policy context of shared decision making in this study, the conceptualisation and models of SDM, and the benefits and outcomes of shared decision making will be presented. The barriers to SDM and the interventions developed to overcome these difficulties thereby enabling SDM to occur, specifically with people who have cancer, will then be examined. This will lead to the introduction of the Navigation intervention that is the main focus of this evaluation study.

The literature review undertaken to inform this chapter was exploratory in nature. As for chapter 2, a structured narrative approach was undertaken, rather than a systematic review methodology. Relevant literature was identified by searching Pubmed, PsycINFO, Cochrane library and Web of Knowledge for publications from 2000 to 2013, and revisited in 2015. In addition the work of key authors in the area and reference chaining were used. In order to ensure all relevant studies were identified, broad search terms were used and included: “shared decision making”, “shared decision making models,” “patient participation”, “oncology”, “cancer”. Specific search terms to explore aspects of shared decision making were used including: “decision aids”, “decision making preferences”, “interventions to support medical consultation”, “prompt sheet”, “coaching”, “question list”, and “measures for decision making”. Articles were screened for relevance using the title, abstract and finally full paper review. The literature is presented here using a structure that explores the broader policy application of shared decision making through to its application at an individual clinical level.

\* the 1980's and 1990's, UK health policy introduced the general public to new concepts of 'user involvement' and 'patient empowerment' (Mead & Bowyer, 2000). Whereas patients were once seen as passive recipients of medical care, patients are now increasingly positioned as 'active consumers' of their healthcare. This re-framing came with new patient rights to expect standards of care that included being fully informed in discussions and involved in the decision making about individual treatment plans (Mead & Bowyer, 2000). Indeed, this position of incorporating patient perspectives into care pathways has been described as the biopsychosocial paradigm of the 21<sup>st</sup> century (White, 1988). Reflecting on health policy since that time it is clear that what was once an innovative move towards shared information and SDM in health care, has now become firmly embedded as mainstream policy features (Coulter & Collins, 2011).

Sharing decision making in health care constitutes the active discussion between, and sharing of, expert information by the doctor, for example the risks and side effects of treatments, and by the patient, for example, patient values and preferences for treatment (Charles, Gafni, & Whelan, 1997). This information exchange is then used to reach a jointly agreed treatment plan. With the emergence of SDM in English health policy already noted, such values are clearly visible in the United Kingdom (Department of Health (DH), 2011; DH, 2012), a similar integration of SDM in Scottish health policy is evident (Scottish Government, 2012). In seeking to map health care provision through to 2020, the ambition for mutually beneficial partnerships between patients and health service deliverers and care that is anchored on clear, compassionate communication and shared decision-making is transparently made clear (Scottish Government, 2012). It can be concluded therefore, that as a mechanism for improving the exchange of relevant, high quality clinical information, SDM is seen as key to



achieving safe and effective care (DH, 2011) and is firmly embedded into National Health Service (NHS) policy (NHS, 2013).

Given the central policy impetus for increased consumer involvement in health care decisions per se, it is unsurprising that strategy directing clinical specialities reflect a similar emphasis: cancer care being one of these areas. Indeed, SDM is seen as key to improving patient experiences of cancer care, cancer treatment and cancer support. This is evidenced by SDM being one of the core principles in a recent UK cancer strategy document (Independent Cancer Taskforce, 2015).

The clinical event most frequently requiring information to be exchanged between patient and doctor is the medical consultation. Consultations between oncology clinicians and the person with cancer shares features common to medical consultations in other medical specialties, for example, discussion about presenting symptoms, diagnosis and treatment options. However, there is an additional emotional burden in cancer consultations caused by: fear associated with a cancer diagnosis; complexity of the medical information involved in cancer diagnosis; uncertainty regarding the trajectory of cancer disease; and concern about efficacy of cancer treatments (Arora, 2003).

It is clear that whilst can be SDM achieved by enabling patients to raise concerns with both patients and clinicians recognising patients as equal partners in care (British Medical Journal, 2011), there are significant challenges in realising this when delivering health care. Within the complex cancer care arena, it is often difficult for patients to understand and articulate their treatment preferences and come to terms with existential matters of life and death (Adelbratt & Strang, 2000). Even if patients with cancer have questions to ask about their

treatment, health care staff are often perceived by patients to be too busy, too afraid or unskilled to discuss matters (Strang & Strang 2001). This is a failing of the current health system where patients with cancer clearly recognise the importance of health care professional's ability to tailor information to their individual information needs (Halkett 2010).

### **3.2 Shared decision making – a conceptualisation**

The conceptualisation of SDM initially arose from acknowledgement that traditional health communication and decision making models needed to be more flexible in order to integrate patients preferences and values. This is especially important in clinical encounters such as the medical consultation where clear and effective communication between the patient and the doctor is required to formulate an individual treatment plan.

When beginning to consider SDM there are some key issues (Clayman & Makoul, 2009) to reflect on: is it the final outcome of the decision that is 'shared' or is the process of decision making that is 'shared'? Following on from this, there are other questions that should be critically considered. Are some clinical contexts more appropriate for SDM? Can SDM only exist in cases with medical equipoise, or should SDM be appropriate and feasible in every patient/clinical situation? Should the patient always accept the position of SDM or can the process of how the patient wants decisions made be discussed and agreed on, even if this includes the patient wanting medical staff to make the decision for the patient?

While a number of SDM models have now been developed, one of the earliest papers to conceptualise SDM in the context of the medical consultation is by Charles, Gafni, & Whelan

(1997). Although nearly two decades old, it is still one of the most cited models in this area (Clayman & Makoul, 2009). The so called ‘It takes two to tango’ model (Charles et al., 1997) defines the three key characteristics of SDM as being:

**(1)** At least two people are involved recognising that the medical encounter is not just limited to doctor and patient, but may include other members of the medical team and relatives, participating through complimentary roles, expectations and behaviours.

**(2)** The doctor must be able to establish a conducive environment that values the views of the patient and elicits patient preferences, transfers technical information to the patients, and assists the patient to conceptualise risk versus benefit in order to share a jointly agreed recommendation.

**(3)** The patient must be willing to engage, disclose preferences, ask questions, balance the information shared, and formulate treatment options with the doctor.

This model suggests it is the process of decision making that is shared, although it does indicate that in turn this will impact the decision outcome. Furthermore the model does not appear context specific. In terms of the communication dynamic, the ‘two to tango’ suggests that the patient should always share equally in the information exchange but that this should be facilitated through the doctor creating an environment that values the sharing of information. This model therefore focuses on a SDM concept whereby expertise is shared throughout all the stages of decision-making process. The doctor, as the expert in the patient’s diagnosis, prognosis, treatment options and their outcome probabilities, shares this information clearly. The patient is the expert in their own medical history, lifestyle and circumstance, personal attitude to risk, and their values and preferences. For SDM to occur, there are reciprocal role expectations in which the sharing of these collective areas of

expertise are used to guide the deliberation and subsequent consensus, where possible, of a decision.

### **3.3 Why shared decision making in cancer?**

The medical consultation provides a unique setting for information exchange. Doctors do not always acquire information about the patient's understanding of their problems and of the patient's physical, emotional and social concerns (Stewart & Roter 1989); and this can be problematic. It is likely that when these areas are ignored in the context of decision making, consideration will not be given to the patient's values or information preferences, and there will be little attention to the patient's understanding of discussions held and decisions made (Silverman, Kurtz & Draper, 2005).

SDM not only has direct impact on the patient's understanding, satisfaction and confidence in the decisions made (Edwards & Elwyn, 2006); greater involvement in decisions can also improve health outcomes. In one longitudinal study conducted in Canada, women with breast cancer reported greater satisfaction with care and improved quality of life, higher physical and social functioning scores and fewer reported side effects when actively involved in choosing treatment than women who indicated passive involvement (Hack, Degner, Watson & Sinha, 2006).

In recognising the principles of SDM during medical consultations, it is generally recommended that clinicians should: inform patients of the type of information that can be provided; elicit how much information a patient wishes to receive; and tailor the clinical information accordingly (Halkett 2009). In recognising that the views and attitudes and needs

of individuals may change, this is not seen as a one-off communication event but rather as an area to be revisited and explored at multiple time points during a series of interactions with the patient (Clayton, 2008).

In acknowledging the potential for patients to refine and change views held about treatments over time and during medical consultations, it is clear that clinical conversations between the doctor and the patient in this setting can be demanding encounters (Stacey, Henderson, MacArthur & Dohan, 2009). One review (Hack, Degner, & Parker, 2005) suggests that both patient and doctor must be confident to engage in the medical encounter: the patient must be confident and not feel vulnerable, while the doctor must be confident in confronting the limitations of what medicine can offer. Effective communication is more likely when doctor and patient can articulate their needs, and respond in a manner that results in both parties feeling understood and heard. This requires a shift from a 'one size fits all approach' in consultation and communication to a more 'tailored' approach that considers the needs of patient and the individual patient's clinical and personal circumstances (Hack et al., 2005).

### **3.4 Barriers to Shared Decision Making**

Despite support from health policy and research for the application of SDM, the implementation and normalisation of SDM into medical consultations remains challenging (Lloyd, Joseph-Williams, Edwards, Rix & Elwyn, 2013). Findings from one American qualitative study interviewing older people who had colorectal cancer (n=73) and their oncologists (n=19), identified that interactions between the doctor and the patient remain still largely paternalistic, reinforcing a passive role for patients (Elkin, Kim, Casper, Kissane, & Schrag, 2007). Given that cancer patients continue to report dissatisfaction with poor communication and unfulfilled information needs (Hack, Degner and Parker 2005), it is

suggested that clinicians need to recognise the extent to which patients wish to be involved in understanding their health problems (British Medical Journal, 2011). Doctors also need to make realistic assessments about the nature and amount of information needed by patients, and possess the developed communication skills to give information in a clear and accessible way (Kinnersley et al., 2007).

There are no parameters or variables that can be used by medical staff to predict how much information patients may want. Patient preference for information and SDM involvement is often difficult to accurately predict with regards to correlation of age, education and gender, often with conflicting evidence in this area. One American study prospectively investigated decision-making preferences in a cohort of cancer patients (n=78). Results demonstrated that 49 patients (63%; 95% *CI* 0.51 to 0.74) preferred a shared approach with physicians and that patient age or sex did not significantly alter decision making preferences (Bruera, Sweeney, Calder, Palmer & Benisch-Tolley, 2001). In another American study (Matsuyama, Kuhn, Molisani & Wilson-Genderson, 2013), the information needs of 138 newly diagnosed cancer patients were studied over nine months using the Toronto Informational Needs Questionnaire. Information needs reduced over time, although gender (women), age (younger), race (African American), education (lesser), and marital status (married) were significantly associated with higher information needs.

There are also practical difficulties that impinge on medical staff engaging in SDM. These have been detailed in an updated systematic review on the barriers to implementing shared decision making into practice from the perspective of health professionals (Légaré, Ratté, Gravel, & Graham, 2008). Using a structured search strategy with quality review processes, 1130 titles were initially identified, resulting in a final 38 studies undergoing full review and

content analysis using a pre-established taxonomy. Physicians were the dominant group reported in the papers (n = 3231, 89%). Concerns about not having enough time was the most frequently cited barrier for doctors when implementing SDM across a number of clinical encounters (22/38). Characteristics of the patient and the clinical setting not conducive to SDM were noted as the second most frequently cited barrier (18/38). Clinicians in favour of SDM only engaged in this process when SDM was perceived to have positive impact on patient outcomes or the processes of care. As such the authors of this study call for the patient's voice to be more overtly supported in the clinical encounter. This may be challenging to achieve if clinicians fear that allowing patients to make decisions that may be against best medical advice and practice, would be incompatible with their medical duty of care (Swenson, Settler & Lo, 2006).

Whilst SDM has considerable currency in today's health care policy environment, the models in use must be influenced by patients' preferences for communication (McPherson, Higginson, & Hearn 2001). Many variables impact on the patient's experience of cancer, particularly with regards to decision making and this may influence the choices they make. There is a latent tension in patients wanting to sustain hope and not feel fearful or anxious and yet wanting to be fully informed with all available information (Leydon et al., 2000). Control and autonomy is central to SDM and yet, at times, patients may wish to avoid information and relinquish control to medical staff as a way of avoiding any decisional regret (De Haes & Koedoot, 2003; Beaver et al., 2005).

Patients may have many valid reasons for not wanting to engage in SDM and to leave medical staff to make decisions. In cancer where uncertainty about the outcome of treatment can be pronounced, deference of decisions to a doctor may be preferred (Shaha et al., 2008).

When illness is literally life- threatening, patients may regard clinicians as having the expertise and power to provide safety (Salander, 2002) and this situation is often reinforced by patient held assumptions that doctors have the patient's best interest in mind (Shaha et al., 2008).

A further influence hindering SDM in health care may be the pervasiveness of the traditional 'passive patient' role. Patients may believe that they do not have the expertise or experience to make, or to contribute to, medical decisions about treatment decisions in life-threatening diseases, due to the complex information used during consultation (Joseph-Williams , Edwards & Elwyn 2014). A European study conducted with women with gynaecological cancers (n=53) examined information needs and decision-making preferences using structured interviews together with measures of information needs (Information Needs Questionnaire) and decision-making preferences (Control Preferences Scale) (Beaver et al., 2005). Results were compared across previously conducted studies using the same tools with breast (n=150) and colorectal (n=42) cancer patients. Participants identified that the doctor was relied on as the 'expert' as patients felt unable to master the complex and technical information involved (Beaver et al., 2005). In addition, participants did not wish to be seen to question medical staff's dominant role and therefore a traditional passive patient role was adopted. Older patients have particularly been reported as holding this view (Bastiaens, Van Royen, Pavlic, Raposo, & Baker, 2007).

Frosch, May, Rendle, Tietbohl, & Elwyn, (2012) in their focus groups (n=6) with patients (n=48) from primary care found similarly the desire to be a 'good patient' is often driven by the fear of retribution in that one would receive less attention if labelled as difficult, and by



the perceived benefits of behaving in a passive manner would make the doctor more sympathetic to needs (Frosch et al., 2012). From this it is clear that having trust in the clinician can act as both barrier and facilitator in SDM. Trust can make patients more willing to ask questions, share information and discuss concerns (Fraenkel & McGraw, 2007) whilst ‘blind’ trust denotes faith that the clinician will do everything in the patient’s best interest enabling the patient to take a passive role as they are in safe hands (Cohen & Britten, 2003).

Patients have also expressed concern about time being a considerable barrier to asking questions, and thereby SDM. Patients were sensitive to the high workload of doctors and felt guilty about taking up the clinician’s time (Frosch et al., 2012). Other practical barriers have been highlighted in a recent systematic review of patient-reported barriers and facilitators to SDM (Joseph-Williams, Elwyn, & Edwards, 2013). Lack of continuity with medical staff seen at clinic was perceived as disruptive and left patients feeling unknown as an individual (Belcher, Fried, & Agostini Tinetti, 2006). Lack of time to adjust to devastating information before making a decision was also noted as a barrier because the consultation could be eclipsed by the shock of receiving a life-threatening diagnosis (Beaver et al., 2005).

The reasons why cancer patients seek or do not seek information from medical staff are complex and cancer patients' attitudes to their disease and their coping strategies can influence their information seeking behaviours and engagement with SDM (Leydon et al., 2000). This results in patients feeling unprepared for consultations with medical staff and patients leaving medical consultations with unanswered questions or inadequate information. Whilst some system-based and practical challenges e.g. lack of consultation time, are difficult to change, attitudinal change in patients towards SDM and their role in decisions about their

health care decisions could be overcome by promoting self-efficacy (Bandura, 1997) in patients. In order for patients to recognise their contribution to, and potential to gain from, involvement in the medical encounter, patients need to be supported to acquire and understand complex medical knowledge and be assisted in being part of the medical decision making process (Joseph-Williams, Elwyn, & Edwards, 2013).

### **3.5 Interventions to Facilitate Shared Decision Making in Cancer**

As previous sections have explored, improving information giving and SDM within medical consultations is challenging. Many developed interventions to facilitate patient-doctor interaction have, to date, focussed on developing the communication skills of doctors (Fallowfield et al., 2002). These have been met with variable success. Such communication training is often based on the traditional assumption that the health professional determines the type, amount and content of information provided to patients and based on understanding of what information patients want. This results in a standardised approach being taken which can have erroneous assumptions when faced with patient populations with potentially heterogeneous information needs. Whilst medical training in communication may inform clinicians of specific communication strategies, communication skills performance remains highly case specific (Baig, Violata, & Crutcher, 2009), implying that the transfer of communication skills from one patient encounter to another is neither obvious nor easy.

Hack et al. (2005) in their examination of communication goals and the needs of cancer patients direct a critical lens on the strategy of strengthening the patient's role in negotiating with clinicians to have their information needs addressed and decision-making preferences acknowledged. Increasing patients' communication skills so that patient goals are met has

potential to result in patients being less reliant on the clinician and more able to satisfy their goals. Enabling patients to effectively communicate personal values, priorities and expectations to healthcare providers and to participate in SDM are of importance here and indeed, are essential elements of patient-centered care (Hibbard, 2003).

Theories of decision making suggest an appropriate decision is one based on the evaluation of the consequences of all options, appraising the likelihood and desirability of these choices accurately and making trade-offs between these evaluations (Bekker, 2009). Janis and Mann's (1997) conflict model of decision making suggests decision conflict arises when individuals experience uncertainty about the decision to make especially when there is risk, regret and a challenge of personal values in the decision options available (O'Connor, 1995). From this perspective, successful decision making consists of vigilant decision making, characterised by the individual's systematic search for information, careful consideration of all viable alternatives and the unhurried, non-impulsive making of the final decision (Janis & Mann, 1997). Without this, patients are likely to overreact and experience regret and even anxiety and rage if undesirable consequences e.g. treatment side effects are experienced (Janis, 1984). Key factors contributing to decision conflict in medical consultation therefore relate patient perceptions of uncertainty, feeling uninformed, decision unaligned with patient values and feeling unsupported in treatment decision making (Stacey, Samant, & Bennet 2014).

One patient-centred strategy to facilitate SDM and to optimise decision making is the use of decision support technologies that can help patients to remember information, focus on points of concern and consider issues for discussion in the consultation (Barnard, Cradock, Parkin, & Skinner, 2007). There are a number of decision support interventions designed to help

cancer patients navigate their healthcare, share decisions and improve communication with their doctors, and these are now discussed.

### **3.5.1 Decision Aids**

Decision aids are evidenced based tools designed to prepare clients to participate in making specific and considered choices about healthcare in ways that they prefer (International Patient Decision Aids Standards (IPDAS) Collaboration, Elwyn et al., 2006). In this way, decision aids are used to supplement and not replace clinician consultations, with the aim of improving the quality of decisions made. Decision aids are intended to bring doctors and patients together in a model of SDM enabling a mutual outcome to be reached that includes meeting the patient's needs.

Decision aids are informed by normative theories of decision making and as such provide a framework for reaching the optimal choice (Bekker, 2009). Expected utility theory, the most widely recognised normative theory of rational choice, postulates “expected utility is a trade-off between the probability of a consequence occurring and the utility placed on that consequence” (Bekker, 2009, p.45). Decision aids seek to minimise this trade-off through the goals of: increased question asking in the consultation; increased recall of information discussed in the consultation; and increased satisfaction and confidence with treatment decisions and decision aids. Often a difference is drawn between decision aids and decision support tools. Most decision aids are self-administered tools, and can be paper or computer-based. Decision aids provide specific and often visual data about the available options to support patients in making an informed choice, for example when a preference sensitive decision has to be made (Stacey et al., 2014). Decision aids present balanced information about specific treatment options available and in sufficient detail for the patient to arrive at an

informed judgement (Coulter and Collins, 2011). This is in contrast to decision support tools that aim to provide patients with greater information, advice and support for treatment and treatment decisions through the use of question prompt sheets, coaching, and recording and summaries of the medical consultation.

A recent Cochrane review of decision aids (Stacey et al., 2014) identified high quality evidence that concludes when compared to usual care, decision aids improve knowledge about treatment options and reduce decision conflict. Moderate quality evidence was reported on demonstrating that decision aids stimulated patients to take a more active role in decision making and improved accuracy of patient perception of risks, when compared to usual care. Low quality evidence was reported to show decision aids improve congruence between the decision and values held by the patient (Stacey et al., 2014). Similar results have been demonstrated in randomised controlled trials using decision aids with cancer patients (Stacey et al., 2008).

Whilst acknowledging the strengths of decision aids, a well-recognised weakness is that decision aids disregard the longitudinal (i.e. over time) and multifaceted nature of health care decision making (Ferrer, Hambridge, & Maly, 2005). Patients, especially cancer patients, are confronted with multiple decisions to make over time, and in the context of developed (or undeveloped) relationships with clinicians. It is recognised that the clinician's opinion about choices is an important and valuable component of SDM itself (Alston et al., 2012) and integrating this into the decision-making process is often beyond the scope of a decision aid.

Rather than using decision aids as a single use tool with a specific aim, an alternative approach would be to address SDM developmentally, as a learned skill and an on-going

process (Ferrer & Gill 2013). This is more in line with the approach taken in decision support tools. Epstein & Gramling (2013) develop this thinking further in their recent work that describes the concept of the ‘shared mind’ in decision making and suggests that difficult decisions are best reached through an iterative process with dialogue involving the perspectives of people important to the patient. Decision aids are often created for situations when there is no clear evidence in favour of one treatment decision over another. In such situations, it is important to consider what current best practice guidelines exist together with the patient preferences (Epstein & Gramling, 2013). Where decision outcomes have high impact, patients often want control over the timing and delivery of the information and are concerned that their values and preferences will be taken into account, but they may not want to make the actual decision themselves (Charles, Whelan, Gafni, Willan, & Farrell, 2003). Whilst it is challenging to ensure all these variables are accounted for in the medical dialogue (Epstein & Gramling, 2013) it is important to develop technologies further to support this outcome. In acknowledging the inherent limitations of decision aids, the evidence base for use of decision support tools is now explored.

### **3.6.2. Questions Prompt Sheets**

One way to enable a patient’s voice to be heard is through the formulation and asking of patient- centred questions during consultation. However, this is an area known to be difficult. Patients are often unaware of what information they require and how much they can ask of their clinician. One way to facilitate patients having more control over the flow of information, is to encourage the asking of questions. Question prompt sheets are effective and inexpensive interventions used in cancer care, enabling patients to become more involved in medical consultations (Kinnersley et al., 2007). In a recent meta-analysis of the empirical literature, small but statistically significant increases in question asking were associated with

significant increases in patient satisfaction (Kinnersley et al., 2007). Question prompt sheets, further supported by other reviews (Dimoska, Tattersall, Butow, Shepherd & Kinnersley, 2008), were originally developed from observation of the medical consultation. Butow, Dunn, & Tattersall (1995) examined 142 interactions between the doctor and patient in the initial oncology medical consultation. Patients were observed to speak for only 24% of the time, and asked a mean of 5.6 questions that took up 0.07% of the total consultation time. In contrast, physicians spoke for 44% of the consultation time, 5% of which was spent answering patient questions.

Low rates of patient questions-asking behaviour results were found in very early work by Roter (1977) when examining the consultation behaviours of 250 general practice patients. Roter (1977) hypothesised that patient's question-asking behaviours could be influenced by addressing enabling, predisposing, and reinforcing factors. Applying this, a coaching intervention was developed to encourage patients to ask questions. In a randomised controlled trial, the experimental group of patients asked more direct questions when compared to controls. However, this concomitantly resulted in increasing negative interactions between the experimental group and the doctor, with lower patient satisfaction report of care received (Roter 1977). Butow, Dunn, & Tattersall (1995) built on this study utilising a randomised controlled trial to investigate the effect of a question prompt sheet to encourage cancer patients to ask questions. No significant difference was identified in the number of questions asked between the control and intervention group, although patients using the prompt sheet group asked significantly more questions about prognosis. These results showed limited effectiveness of these interventions to increase question-asking behaviour in patients.

Learning from previous trials, Brown, Butow, Boyer, & Tattersall, (1999) ensured the prompt sheet used in their study was discussed with and endorsed by the clinicians, and added individualised coaching to train patients in question-asking behaviours. Research psychologists worked with patients immediately before their consultation on the importance of asking questions, guided them to generate a list of questions, explored benefits and barriers to questions asking and, using coaching techniques, invited them to role play asking their questions. Results demonstrated that the intervention groups did ask more questions, but this outcome was not statistically significant.

In a more recent trial, although still not current, a heterogeneous sample of cancer patients (n=318) were randomised to receive a question prompt sheet or not (Brown, Butow, Dunn, & Tattersall, 2001). Oncologists were also randomised to either actively address the prompt sheet or passively respond in their consultation. Patients in the intervention group and who used the prompt sheet asked more questions about prognosis when compared with the control group and this resulted in oncologists offering more prognostic information to these patients ( $p=0.058$ ). Patients who had a prompt sheet and a proactive doctor recalled significantly more information and had significantly shorter consultations. Patients with the prompt sheet and a passive doctor were reported as significantly more anxious than the two other groups, suggesting if a prompt sheet is utilised, the clinician's endorsement is key to preventing a negative reaction. Conclusions from this study are difficult as the sample was heterogeneous and although large, there may have been a large variance in the nature of topics discussed. This is reflected in the duration of consultation times, cited as 8 – 78 minutes.



A recent cross over trial based in primary care in Australia, aimed to test the effectiveness of just three generic questions hypothesised to elicit the minimum amount of information needed to make a decision (Shepherd et al., 2011). These questions included: What are my options? What are the benefits and harms? And, how likely are these? (Shepherd et al., 2011). This study utilised two standardised patients, one delivered the intervention whilst the other provided the usual care condition by not asking the prescribed questions. Thirty-six unannounced standardised patient visits (18 intervention, 18 control) to primary care were conducted. The transcripts of each consultation were then analysed using a non-standardised measure of patient involvement (Assessing communication about evidence and patient practice, ACEPP) and the well validated coding tool OPTION (Elwyn et al., 2005) to measure clinician involvement. Rater analysis demonstrated within the intervention group consultations, there was improved information provided by the clinician and increased consideration of patient preferences in regards to treatment decisions thereby enhancing patient involvement (Shepherd et al., 2011). This study presents powerful effects of three simple questions on clinician's communication behaviour, however the reliability of the ACEPP tool is not well established.

From this review of question prompt sheets, it is clear that encouraging patients to ask as much as they wish or do not wish, supported by the clinician, is integral to their success. The negative impact on patients when using prompt sheets is a worth consideration. Salmon (2005) cautions that prompt sheets could disempower patients by inducing them to participate more than they may have initially wanted to. It is postulated that there is a fine line between empowering patients to achieve their goals and training them to fit with current thinking of the SDM role for patients (Salmon, 2005).

### **3.6.3. Patient Coaching**

The focus of coaching techniques as a decision support tool are in line with the core patient-centred SDM principles outlined previously. Therefore coaching focuses on enabling patients to speak up about their concerns, question what is important to them, recognise their right to be equal participants in care, and to seek and use high quality information.

A Cochrane review has assessed the evidence of impact from interventions to help patients address their information needs before their consultation, using a narrative synthesis and meta-analysis (Kinnersley et al., 2007). This review identified 33 eligible RCTs, of which the most common interventions were checklists and patient coaching. Meta-analyses demonstrated these interventions were statistically significant in increasing question asking and patient satisfaction. Interestingly, although not significant, the authors found anxiety decreased before the consultation and again afterwards. Notably the addition of coaching to an intervention before the consultation produced a larger non-significantly increase in patient satisfaction when compared to the prompt sheet alone (Kinnersley et al., 2007). Furthermore, the use of coaching and written materials such as question prompt sheets produced a smaller increase in the length of the consultation when compared to question prompt sheets alone (Kinnersley et al., 2007). In further support of this finding Belkora et al. (2008b) interviewed coaching staff who reported “because of my work [coaching], the doctor can learn key things about a patient in five minutes [by reading the prompt sheet] that I've learned in an hour and a half” (p.5). These findings suggest the use of the coach in addition to written materials does provide an added benefit to patients, and potentially the medical staff.

Several rationales were conceived from a review ( $n=96$ ) of the theoretical and empirical evidence to inform the use of coaching alongside tools of decision support (Stacey et al., 2013). These rationales included the ability of coaching to; achieve higher quality decisions, avoid decision pitfalls, improve the quality of two way communication between patient and clinicians, enhance learning and manage emotional distress (Stacey et al., 2013). When compared to usual care the authors found coaching improved knowledge, however all other variables (participation in decision making and satisfaction) were no different, and no worse, than interventions without coaching. The authors concluded that the theoretical evidence justifies the use of coaching to enhance decision support for patients and facilitate their involvement in shared decision making (Stacey et al., 2013).

#### **3.6.4. Recordings and Summaries**

Whilst the provision of information in different formats is recognised as important (Halkett, 2010), the most effective way for providing information for cancer patients is as yet unclear (Catt et al., 2008). Evidence suggests that while cancer patients with a good prognosis find a taped or written record of the consultation helpful, cancer patients with a poor prognosis do not benefit from holding a detailed reminder of the ‘bad news’ consultation (Cancer Guidance Subgroup, 1998).

It is often difficult for any patient to remember all the information that is presented in a consultation (Kawabata, Konishi, Murakami, Kisa, & Maezawa, 2009). For this reason, many patients access information outside of the medical consultation, for example at home, through use of internet. Whilst some of these resources can be high quality, others may contain information too general for individual patients, and some may even convey misleading,

inappropriate or confusing material. One way to circumvent this problem is to provide only information that is applicable and specifically tailored to meet the individual patient's information needs. This can be achieved by providing patients with a recording of their medical consultation that can then be taken home for review in their own time (Butt, 1977).

Reviews of the empirical evidence support the conclusion that recordings and summaries of oncology consultations are valued and utilised by patients, improve patient information recall and potentially enhance patient satisfaction (Pitkethly, MacGillivray & Ryan, 2008; Tattersall & Butow, 2002). As a Cochrane review, the results of 16 randomised controlled trials involving use of recordings or summaries of consultation were studied. There was no evidence of increasing anxiety and depression in patients following the use of recordings or summaries, with indication that recorded information was used to later initiate treatment discussions with family members (Pitkethly et al., 2008). This Cochrane Collaborative Group concluded that although more research was needed to improve understanding in this area, the provision of recordings of key consultations may benefit adults with cancer, and that practitioners should consider offering consultation recordings to patients (Pitkethly et al., 2008). Indeed, this has been supported by SIGN guidance (2011) for treating patients with colorectal cancer, recommending that healthcare professionals should consider giving written summaries or recordings of consultations to those who have expressed a preference.

Providing recordings or even sending patients their clinic letters is not standard medical practice in some health care systems, such as in Scotland. Whilst no studies have reported clinician's expressing concern in having their consultation recorded, work in this area is outdated and non-UK based. Two surveys in Australia (Tattersall, 1994; Stockler 1993) reported neither doctors nor the medical defence organisations were concerned about the

legal consequences of providing patients with a recording. Differences in the benefits of providing recordings and/or providing summaries has not been widely or recently studied (Pitkethly et al., 2008). Two studies have reported that a recording was more effective than written information (Tattersall Butow, Griffin, & Dunn, 1994; Bruera Pituskin, Calder, Neumann, & Hanson, 1999) but further work is required in this area to determine whether one medium is more effective than another, or if both are required. Furthermore, the majority of studies investigating the usefulness of audio-recordings for patients have focused on the initial meeting between patient and doctor, specifically bad news consultations. Given that treating patients for cancer can be a long process with multiple decisions throughout the disease course, at each appointment, new information and options may be presented. This needs appreciation in the design of studies evaluating use of such recordings.

### **3.7. Consultation Planning, Summarising and Recording (CPRS): Navigation**

Navigation is a decision support and communication tool designed by Belkora (2005) to facilitate breast cancer patients make decisions about their treatment options. As a complex intervention Navigation brings together key elements described above, namely: question prompt sheet, coaching, and provision of a recording, in addition it also provides a written summary of the consultation. The intervention was derived from original work undertaken about consultation planning, recording and summarising (CPRS) and the first evaluation of the intervention in full was published in 2008 (Belkora et al., 2008). CPRS follows guidance from the Ottawa Decision Support Framework, an evidence-based, practical, mid-range theory that guides patients making health or social decisions (<https://decisionaid.ohri.ca/odsf.html>). The framework proposes that decision support interventions should assess patient decision needs; address those needs; and measure

outcomes including decision self-efficacy, decisional conflict, and decisional regret, among others (O'Connor et al., 1998).

The CPRS intervention identified patient needs for asking questions and remembering responses during medical consultations (Hack et al., 2005; Rutten et al., 2005) and combines evidence-based interventions (question-listing, note-taking, and audio-recording) with coaching to address these needs (Kinnnersley et al., 2007; Pitkethly et al., 2008). As it addresses common patient information and communication needs using evidence-based strategies, CPRS has been transferable to distinct contexts. Studies have found the CPRS or Navigation intervention to be effective in breast cancer (Belkora et al., 2015); prostate cancer (Hacking et al., 2013); and orthopedics (Bozic et al., 2013). These prior experiences with CPRS established its feasibility and effectiveness across a broad range of clinical conditions.

CPRS has a strong evidence base of facilitating communication and decision making in breast cancer consultations in America, specifically aiming to increase question asking by patients during treatment consultations, improve patient knowledge and recall of treatment information provided by the physician, and significantly increase confidence in and satisfaction with the final treatment decision (Belkora 2008a; Belkora 2008b; Belkora 2009). Furthermore, it has been demonstrated to significantly reduce patient reported communication barriers in the medical consultation (Sepucha, Belkora, Mutchnick, & Esserman, 2002).

The intervention consists of three evidence-based practices combined into one patient-centred intervention. Navigation involves question listing, audio recording and summarising.

‘Navigators’ who are staff trained in the intervention, guide patients through the process. Navigators meet with patients over the phone and help them to generate a list of questions and concerns. This is known as a consultation plan for use in their medical consultation. This list is generated using a neutral non-directive approach to question listing (Belkora 2008a; Belkora 2008b, Belkora 2009), known as SCOPED; Situation – Choices – Objectives – People - Evaluation – Decisions. Patients are encouraged to think of questions which are then organised into a list under the SCOPED topic headings. This list is then given to the patient’s clinician to review before the consultation occurs. The Navigator then accompanies the patient to their consultation. Consultation recordings consists of the Navigator creating a CD audio-recording of the patient’s conversation with their consultant. Consultation summarising consists of the Navigator creating a word processed written summary of the key advice and information presented by the doctor during the visit.

Navigation was first trialled in the UK with newly diagnosed prostate cancer patients in Edinburgh, Scotland from 2008-2010 during patient’s initial oncology consultation (Hacking et al., 2013). The feasibility and efficacy of this trial was tested utilising a concurrent mixed two arm methods randomised controlled trial. The quantitative analysis from patient pre-post- questionnaires revealed that Navigated patients ( $n = 62$ ), compared with usual care patients ( $n=52$ ), had significantly higher scores in decision self-efficacy ( $p<0.05$ ) in addition to significantly less decisional conflict ( $p<0.05$ ) about treatment decisions post-consultation. Navigated patients further experienced significantly less decision regret ( $p<0.05$ ) 6 months after intervention, where higher levels of self-efficacy were maintained in favour of Navigation (Hacking et al., 2013). Effects on mood or anxiety were not found, suggesting that Navigation did not impact on this area. This study is currently the only randomised controlled trial of Navigation and more work is needed to validate results of this trial.

This study also had a qualitative component where six intervention patients were interviewed regarding their experiences of Navigation (Hacking, Scott, Wallace, Shepherd & Belkora, 2014). Findings demonstrated that Navigated patients felt enabled to prepare for the medical consultation, and used the question list to help them focus on their concerns in the consultation. They reported that the doctor was prepared for them and presented them with individualised information. All six participants reported utilising the CD and summary and found them useful to help with recalling information and facilitating the choice of treatment options. Patients also reported they felt supported by their Navigator, although the definition of what this support encompasses is not provided. These findings suggest Navigation with prostate patients was well received and benefitted the patient in a SDM process. The small sample (6 from 63 intervention trial patients) is acknowledged as a limitation and with no control sample for comparison it is difficult to draw conclusions from this qualitative study in isolation.

By including a qualitative component in their randomised controlled trial Scott et al., (2014) were also able to evaluate Navigation in terms of its effectiveness from the perspective of the specialist doctors (2 oncologist, 2 surgeons). From this, doctors reported that Navigation patients were more prepared for their consultation meetings and doctors reported being more prepared to see patients, having reviewed their consultation plan. Doctors reported using the consultation plan as a checklist at the end of the consultation to ensure concerns were addressed. These findings are consistent with previous studies (Belkora et al., 2008b) in that Navigation helped patients organise and clarify their medical questions and ensure these were attended to by doctors, who were able to plan how to conduct the consultation with prior



understanding of the patient's information needs. This latter point support is also noted as an advantage for clinicians in a review paper on health care consumer support by Hibbard (2008). Whilst medical staff supported the use of Navigation into the UK healthcare system with prostate cancer patients (Hacking et al., 2014), the implementation cost of this was seen to be prohibitive, with alternative ways of implementation suggested, including utilising Clinical Nurse Specialists or volunteers. Currently, in America the program is delivered through a less costly premedical internship programme.

In this short introduction to Navigation, it can be seen that previous research has only undertaken Navigation with two oncology patient populations, and at one time point within their medical journey. Consequently, to progress learning about this intervention, its effectiveness, credibility and sustainability, this thesis is designed to trial Navigation with a more diverse oncology population and follow patients over consecutive consultations, over time as medical choices and decisions evolve.

### **3.8. Summary**

This chapter has reviewed the health policy drivers and current literature based on shared decision making demonstrating the increased focus on shared decision making, particularly with regards to cancer care. The empirical evidence exploring patient needs for information and the practical, professional and social barriers in achieving this have been explored. Finally patient-centred interventions, specifically decision support aids, designed to facilitate patient involvement in their consultations have been described and the Navigation intervention evaluated in this thesis was introduced. The next chapter will present the overarching design of this study that was used to evaluate the Navigation intervention.

## **Chapter 4: Study design, Navigation intervention and protocol**

### **4.1. Overview**

The previous chapter set the scene for this study by exploring literature relevant to shared decision making in an oncology context. This chapter outlines the study design, the intervention and the sample populations for this thesis. The study design describes the approach taken to evaluate the Navigation intervention. The intervention model will then be described in-depth using the template for intervention description and replication (TIDieR) checklist and guide (Hoffman et al., 2014). The chapter concludes by presenting an overview of the evaluation time points across both samples and within the two empirical studies conducted that evaluated the Navigation intervention.

### **4.2. Study Design**

A mixed-methodology design employing a parallel group, pragmatic randomised controlled trial (RCT) with nested qualitative studies was utilised to evaluate Navigation. The study was longitudinal in nature with six measurement points over nine months evaluating serial exposure to the intervention, repeated three times. Whilst the RCT evaluation was longitudinal, the qualitative evaluation occurred at one time point, at the end of treatment. The qualitative evaluation included participants and their clinician's perspectives. The rationale for this design is presented below. Details relating to the RCT will be described first followed by separate description of the qualitative evaluation.

### **4.3. Evaluating a complex intervention: a mixed methods approach**

The UK Medical Research Council (MRC) (2000) proposed a framework for the development and evaluation of complex interventions, subsequently updated by Craig et al. (2008). Navigation, as previously described is an intervention comprising of several different

types of decision support interventions. Navigation therefore is a complex intervention, as defined by the MRC framework (Craig et al., 2008). When evaluating complex interventions, methodological design is driven by establishing effectiveness in everyday practice (Craig et al., 2008). The older MRC guidelines (2000) provided guidance for evaluators to ensure a logical and systematic progression of evidence was built through the design of research studies. This guidance was used to steer the methodological design of this evaluation of Navigation. As Navigation is a ‘technology’ already in existence and with a body of supporting literature that has undergone exploration and testing through use of mixed methodology; sequential controlled trial (Sepucha et al., 2002), case study (Sepucha, Belkora, Aviv, Mutchnik & Esserman, 2003) qualitative evaluation (Belkora et al., 2009, Hacking et al., 2013), quasi-experimental (Belkora et al., 2013) and RCT (Bozic et al., 2013; Hacking et al., 2013) studies. The MRC guidance suggests that this body of work is currently at a Phase III, exploratory trial, of the evaluation trajectory as show in Figure 4.1.

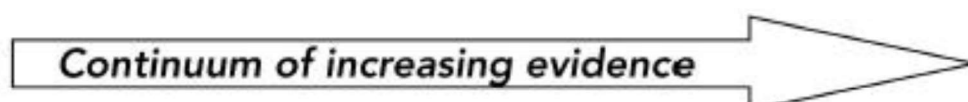
**Figure 4.1** The MRC framework for the evaluation of complex interventions (MRC, 2000,

p3.)

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thesis can be found in the Lancaster Library, Coventry University.

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To comprehend which methodological design will best meet aims of this study an understanding of the paradigm stances is first needed. Distinction is often made between ‘qualitative’ and ‘quantitative’ methodology. The terms are often used to describe competing philosophical views about the nature of knowledge in the social world and the ways in which social reality should be studied (Guba & Lincoln, 1982). The terms are also used to describe different ways of conducting social investigations described as a technical position (Bryman, 1992). Academics continue to argue the merits and demerits of positivism (which equates with quantitative and objective methods) and of naturalistic inquiry (which equates with qualitative and subjective methods). Furthermore, they are often seen as being in competition with each other. Within health care this competition has arisen as a consequence of the evidence based medicine approach and the search for evidence that is reliable and generalisable to a population (McPherson & Leydon, 2002). Quantitative methodology has secured a dominant role in the provision of evidence within the health system.

Quantitative methodology generally emphasises theory testing and an external perspective of a single tangible reality (Lathlean, 1995). In contrast, qualitative research is marked by a concern with the discovery of theory rather than the verification of theory (Filstead, 1979). The qualitative paradigm argues that social settings are complex, made up of individuals with different perspectives, behaviours and intentions and can only be understood by studies that reflect this experience, that value the ‘lived experience’ of those within it and the meanings that actors attach to their behaviour (Burgess, 1984). The aims are to analyse and describe experiences, values and attitudes of people in their natural contexts (Burgess, 1984) with an understanding of the role of the researcher within the data collection process. Qualitative methods in health care are becoming widely used and increasingly accepted (Mays and Pope, 2000). However, qualitative research in the field of cancer has often been low on the

hierarchy of methodologies due to its small sample size and therefore lack of generalisability (McPherson & Leydon, 2002). To reject this methodology, which aims to understand the lived experience of cancer in favour of a reductionist approach is limiting in the pursuit of providing patient-centred care.

The MRC guidance suggests a combination of qualitative and quantitative methods is likely to be needed, for example ‘to understand barriers to participation and to estimate response rates’ (Craig et al., 2008, p10). Mixed methods investigations involve the integration of qualitative and quantitative data collection and analysis in a single study (Creswell, Plano Clark, Gutmann & Hanson, 2003). The concept of using mixed method research is gaining popularity within the social science and health field (Gutterman, Fetters & Creswell, 2015). This integration of methods is particularly important when studying oncology as “understanding the psychosocial aspects of living with a cancer and the related increasing complexity of providing appropriate and timely cancer care is increasingly being developed across Europe” (McPherson & Leydon, 2002, p.225). Silverman (2001) suggests that when considering methodologies, the common goal of both methodologies in detecting patterns in data based on the analysis of the data body, should be recognised. Sandelowski (2000) states that it is the researcher’s orientations to inquiry and methodological commitments that should influence how they are utilised.

Mixed methodology to evaluate an intervention is characterised by “concurrent use of quantitative and qualitative data collection to facilitate data triangulation and evaluate programs in a comprehensive way” (Natasri, 2007, p14). Mixed method evaluation aims to assess program acceptability, application to daily life, cultural specificity, integrity and quality of the active intervention and any immediate or long term outcomes (Nastasi, Moore

& Varjas, 2004). The use of multiple paradigmatic approaches is particularly useful in the evaluation of the effects of complex health interventions, such as Navigation, as this involves behavioural processes that can be difficult to explore or capture using quantitative methods alone (Lewin, Glenton & Oxman, 2009).

The motivations of early mixed methods work were driven by the pursuit of a cross-validation of results; conducting two different studies with the goal of reaching the same conclusions (Campbell and Fiske 1959, Glantz, Halperin & Hunt, 1998). This aim however is both expensive and time consuming. Complementarity has since consistently been a strong motivation for combining research methods. Here the strength of one method is used to enhance the performance of the other method. The mixture of qualitative and quantitative evaluation is often needed in the evaluation of complex interventions to gain further insight into barriers to participation or counter-intuitive findings (MRC, 2008). This thesis utilises the convergent design model to guide the quantitative and qualitative approaches of this study (Gutterman, Fetters & Creswell, 2015). This model involves collecting qualitative and quantitative data concurrently (Gutterman, Fetters & Creswell, 2015). The two forms of data are then be integrated through merging the quantitative with the qualitative results in the discussion (Gutterman, Fetters & Creswell, 2015). The quantitative and qualitative approaches chosen for this study, steered by the revised MRC guideline are discussed in the following section.

#### **4.3.1. The Qualitative and quantitative design**

The MRC revised guidelines (2008) on complex interventions suggest that the parallel-group randomised controlled trial is the optimal study design to minimise selection bias and provide the most accurate estimate of benefits. Randomisation fundamentally depends on the

statistical power of chance to evenly distribute potentially confounding variables among the trial arms (Craig et al., 2008). Where confounders are minimal and participant numbers high, this strategy should be adequate.

For this study, a parallel-group randomised design with the colorectal cancer population was feasible. However, this design was not feasible within the population of people diagnosed with a High Grade Glioma due to the rarity of this cancer type. Furthermore, longitudinal RCTs are particularly difficult to implement in trials of interventions within this population because of high rates of attrition due to death (Catt et al., 2008). Within the colorectal population it was estimated, based on previous evaluation trials of Navigation, that the study would be sufficiently powered to reliably identify any difference between the trial arms (intervention vs. control). The advantage of utilising randomisation ensures the effects of any external factors such as environment / demographics, which may influence outcomes, were minimised thereby reducing any selection bias that may have been present. However, it is possible for confounding factors, especially if uncommon but significant, to be more prevalent in one arm over another (MRC, 2000).

As noted previously the MRC guidelines (2008) suggest a qualitative element of evaluation is integral to the understanding of how the intervention is experienced and implemented from the perspective of its users. Within this evaluation qualitative data from trial participants and consulting clinicians were gathered to triangulate the RCT results. By gathering both forms of data, the study aimed to provide a comprehensive and complete understanding of the intervention. Furthermore, for the evaluation of the intervention from the perspective of the HGG population a qualitative evaluation design was also feasible. This provided a

comparison of experiences with the intervention across populations. Justification and elaboration on this qualitative design is discussed in-depth within chapter 7.

A review of RCTs which utilised qualitative approaches by Lewin et al. (2009) emphasised the importance and contribution of qualitative studies to RCT designs. This review found 19 out of 100 trials published qualitative work and only four of the qualitative investigations were conducted after the trial (Lewin et al., 2009). Utilising the critical appraisal skills programme to review the quality of the qualitative studies the review found no integration of the two approaches (qualitative and quantitative) in the analysis or interpretation in 13 trials (Lewin et al., 2009).

This study is guided by the convergent design model (Gutterman et al.'s (2015) to ensure integration of the results meets the necessary aims of the evaluation. As such, the study structure and methodology will present quantitative data collection, analysis and results (chapter 5 and 6) separately from the qualitative data collection, analysis and findings (chapter 7, 8 and 9). Integration of this data will occur when the results of the study are discussed (chapter 10), thereby presenting an enhanced understanding of the impact of the intervention on the treatment for cancer, a feature found lacking in a previous review (Lewin, Glenton & Oxman, 2009). Further justification for the specific methodologies will be presented in the study-specific chapters (5 and 7).



#### **4.4. Study Setting**

As detailed previously, a mixed methods evaluation of Navigation was conducted by undertaking a RCT with a cohort of CRC patients alongside and a qualitative evaluation with a cohort of HGG patients. This evaluation was conducted in a tertiary cancer centre in Scotland. The centre is a regional cancer centre and the sole provider of specialist cancer services to a geographically defined population of approximately 1.5 million people (Strong et al., 2007).

The RCT took place between November 2010 and December 2013 in the colorectal cancer clinic. This clinic is staffed by colorectal oncologists and typically diagnoses 190 new cases of CRC each year, and of these five to six people are referred for further oncology treatment. The qualitative evaluation took place between November 2010 and January 2013 in the neuro-oncology clinic. This clinic is run by medical staff from neurology, neurosurgery and oncology specialities and typically diagnoses 100 new cases of HGG each year.

#### **4.5. Ethical Approval, data management and study funding**

Although typically ethical approval is explored later in the methods chapter, due to the complex design of the study, the ethical arrangements are made clear at this point. NHS ethical approval was obtained from the South East Scotland Research Ethics Committee 03 REC reference number; 10/S1103/47; see Appendix 1. The study was also approved by the Queens Medical Research Institute, Research and Development, project number; 2010/W/ON/19 and Coventry University Registry Research Unit. All data records were anonymised and held according to the requirements of the Data Protection Act (1998) and Caldicott Guardian principles. Questionnaires and consent forms, were stored in separate

locked cabinets. Recordings, consultation plans and summaries were stored in a NHS secure electronic database with no identifying details included.

#### **4.6. The Navigation intervention**

To give structure to the reporting of Navigation, the complex intervention that is being evaluated in this thesis, the Template for Intervention Description and Replication (TIDieR) checklist and guide (Hoffman et al., 2014) is utilised. Making transparent the structure and application of interventions is important. Complex interventions have been labelled ‘leaky’ in nature i.e. their form may not always be the same (Pawson, Greenalgh, Harvey & Walshe, 2005). In a review of complex interventions by these authors, it was suggested there would be some inevitable change in the delivery of a complex intervention “delivered in a mutating fashion shaped by refinement, reinvention and adaptation to local circumstances” (Pawson et al., 2005, p23). The occurrence of this ‘leaky’ nature is less important than the acknowledgement and reporting of the changes to intervention delivery and content.

The reporting of complex interventions often lack the detail needed to enable replication. An analysis of 137 RCTs of non-pharmacological interventions published in 2009 in leading general medical journals identified that over half (61%) did not provide the level of detail needed to enable replication of the complex intervention in practice (Hoffman, Eructi & Glasziou, 2013). This may be unsurprising given the guidelines for reporting interventions have only recently been developed. One approach often used to report and describe complex interventions is the CONSORT checklist for reporting non-pharmacologic RCT evaluations (Boutron, et al., 2008). As a reporting structure, the CONSORT checklist identifies four key areas to guide the description of interventions including: trial arms, intervention components, standardisation and adherence. In contrast, the TIDieR checklist is more focussed on reporting the intervention design by describing the intervention using twelve items, each with

sufficient explanation with an illustrative example sufficient to enable replication (Hoffman et al., 2014).

The TIDieR checklist was developed through using results from a literature review for pertinent checklists, followed by a Delphi survey of an international experts to guide item selection, and a face to face panel meeting to agree the final checklist structure and content (Hoffman et al., 2014). The resultant 12 item TIDieR checklist includes details of the name of the intervention, the materials used, the procedures, planning and delivery of the intervention. It is in fact an extension of the previously developed CONSORT 2010 statement (item 5) and the SPIRIT 2013 statement (item 11). The strength of utilising the TIDieR checklist is that it is specific to detailing the design and procedures of intervention studies, as opposed to the CONSORT guidelines which provide structure for reporting on trials.

In using the TIDieR framework to report on the intervention, sufficient detail is therefore provided within this thesis to enable replication. The remainder of this chapter uses the TIDieR checklist to detail reporting on the complex intervention. This thesis also includes a completed copy of the TIDieR checklist (Appendix 2).

#### **4.6.1. Navigation**

The intervention is called Navigation and comprised three evidenced-based processes: consultation planning (Kinnersley et al., 2007), audio recording, and summarising (Pitkethley, MacGillivray & Ryan 2008). In publications, the intervention has been referred to as CPRS an acronym for consultation planning, recording and summarising (Belkora et al., 2015), and Decision Navigation (Hacking et al., 2013). Through discussion with Belkora (personal communication, 2010) it was decided to remove the word ‘decision’ from this study

as it did not appear reflective of all the components of the intervention. The term ‘Navigation’ was maintained to allow for recognition and continuity between the current and previous studies (e.g. Hacking et al., 2013). Participants were invited to take part in the ‘Patient Information Navigation’ study.

#### **4.6.2. Theory essential to the Intervention**

The Navigation intervention follows the underpinning principles of the Ottawa decision support framework (ODSF) (O'Connor et al., 1998). This framework proposes that decision support interventions should assess patient decision needs; address those needs and measure outcomes (O'Connor et al., 1998). The framework was designed to guide the development of shared decision making interventions and is a combination of several decision making theories; the expectancy value model, decision analysis, prospect theory, conflict theory of decision making and theory of reasoned action (described in Chapter 3, section 3.6.1) (O'Connor et al., 1998). In essence, the framework is based on the premise that when making decisions an individual is more likely to opt for the option with the highest expected values and success; choices are made based on the probability of consequences (and the utility of this consequence); the choice may be influenced by how it is framed; uncertainty in choosing can be relieved by the gathering and evaluation of information, and decisions are made based on our attitudes and subjective norms. The ODSF is organised according to determinants of decisions, with different elements of the intervention addressing each determinant and its evaluation (O'Connor et al., 1998). It is hypothesised that improving the quality of decision making may have a favourable impact on patient outcomes (O'Connor et al., 1998).

The ODSF framework begins by recognising that determinants of any decision include the clinician and patient's perceptions of the decisions together with any important others

involved, their personal and external resources to make and implement a choice and personal demographics (O'Connor et al., 1998). This foundation drives decision support interventions to improve decision making quality by influencing the modifiable determinants (O'Connor et al., 1998). The Navigation intervention specifically focuses on addressing the information needs and recall abilities of oncology patients when making decisions (Hack et al., 2005; Rutten et al., 2005). It combines evidence-based interventions (question-listing, note-taking, and audio-recording) with coaching to address these needs (Kinnersley et al., 2007; Pitkethly et al., 2008). In this way, the intervention addresses the determinants of inadequate knowledge, inadequate support, unrealistic expectations, unclear values and inadequate personal resources in the patient to make a decision (O'Connor et al., 1998). The general theoretical underpinnings of the ODSF, and the specific conceptual goals of Navigation were used to inform the outcome and process measures used in this evaluation of the Navigation intervention. The specific research questions and outcome measures will be further explored when discussing the variables evaluated in the RCT (Chapter 5), and also informed development of the interview schedule used to collect data in the nested qualitative study (Chapter 7).

#### **4.6.3. Materials and procedures**

The Navigation intervention was delivered by two trained Navigators who delivered the intervention across both patient populations. The methods for each of the Navigation stages are detailed below.

##### **Consultation Planning**

Consultation planning denotes the time that the Navigator spent with patients prior to medical consultation in the oncology outpatient clinic. In meeting with the Navigator at this time,

planning for the medical consultation was undertaken by way of thinking about questions and concerns that patients want to raise with medical staff. The outcome of the consultation planning appointment was a patient formulated consultation plan sent in advance to medical staff for use in the upcoming oncology consultation. In the majority of cases, this meeting took place with their Navigator over the telephone in order to avoid additional hospital visits. Where patients expressed preference for a face-to-face meeting, the Navigators met with patients in a quiet room in the hospital or local cancer support centres. Consultation planning meetings lasted 30 minutes (approximately).

For the purposes of this evaluation, a maximum of three consultation planning meetings occurred. That is a meeting with Navigators occurred before three consecutive outpatient clinic appointments. At the first encounter of consultation planning, Navigators familiarised participants with the process and procedures of the consultation planning session and set appropriate expectations for the duration of the evaluation. This conversation was audio-recorded, with the participant's permission, thereby enabling Navigators to listen to the conversation and ensure all pertinent information was delivered. This audio-recording was also used for quality assurance procedures. It was stored securely on a shared drive in the hospital system, only accessible by the research team.

Navigators began each consultation planning by asking participants to explain what had happened with their oncology care to date. To facilitate a participant's critical reflection of their current and upcoming situation, Navigators used neutral, non-directive interviewing technique known as 'SLCT' (<http://www.slctprocess.org/ref>). This helped patients formulate issues and involved four steps:

1. **Scribing:** Participants were guided to freely talk about their situation and what had happened while the Navigator typed brief notes/ bullet point list on a computer/laptop.
2. **Laddering:** This step used the Ladder of Inference ‘Strategy, Change and Defensive Routines’ (Arhyris, 1985). Navigators guided patients to elaborate on any issues noted in the scribing step, leading to more specific, concrete statements. The outcome of this step was to make explicit any implicit thinking of concerns or fears.
3. **Checking:** Using a specific, structured question prompt sheet known as SCOPED, developed by Dr Jeff Belkora at UCSF (see appendix 3), Navigators guided participants in formally creating their ‘Consultation Plan.’ Navigators encouraged participants to think about key questions, concerns and objectives relating to the six categories of the SCOPED model: their current Situation, the treatment Choices available to them, their personal goals and Objectives for treatment and their quality of life, the People involved in supporting them, Evaluating the impact of their choices against their personal objectives, and finally the Decisions that they have made or will need to make in the future regarding their care.
4. **Triaging:** In the final step participants were guided to prioritise issues according to their level of importance for their next clinic appointment with their consultant.

During consultation planning, the Navigator made typed notes about the content of the consultation, to ensure all the patient’s key questions and concerns were recorded. At the end of consultation planning (CP), the Navigator clarified the patients’ key questions and concerns, and took verbal permission from the patient to forward this information, known at the consultation plan, to their oncology consultant prior to the appointment.

## **Outcome**

The outcome of this appointment was the consultation plan – a written document including the patient’s concerns and questions using the SCOPED structure. An example of a

consultation plan can be found in Appendix 4 and below in figure 4.2. Consultation plans were securely emailed (using NHS email accounts with encryption) prior to the appointment for the attention of the consultant. Participants received an email copy of the consultation plan with all questions highlighted in bold text to make them easier to identify during the consultation. In addition, reception staff were provided with a hard copy of the plan to attach to patients notes on the day of the clinic.

**Figure 4.2.** *A consultation plan: An anonymised consultation plan for a HGG participant's initial appointment.*

<p><b>Situation</b> (key facts)</p> <ul style="list-style-type: none"> <li>• Bumping into things in the street and had sinus pain – GP said it was the effects of a virus.</li> <li>• 2 weeks later GP realised something more than a virus, referred me for MRI</li> <li>• I don't remember much, but I was told by the surgeon that I had a tumour</li> <li>• <b>What is my diagnosis? What type of tumour do I have?</b></li> <li>• <b>What are the results of the tests following surgery?</b></li> </ul> <p><u>Current Symptoms</u></p> <ul style="list-style-type: none"> <li>• <b>My hearing in my left ear has diminished by 50% since the weekend.</b></li> <li>• I am not sleeping well.</li> </ul> <p><u>Current Medication</u></p> <ul style="list-style-type: none"> <li>• I take steroids, anti-epilepsy drugs, <b>how long should I continue this current medication?</b></li> <li>• <b>Whilst I am taking medication, is it safe for me to be on my own with the children?</b></li> </ul> <p><b>Choices</b> (available actions)</p> <ul style="list-style-type: none"> <li>• <b>What are the treatment options available to me now?</b> <ul style="list-style-type: none"> <li>◦ How long will they last? What are the side-effects?</li> </ul> </li> </ul> <p><b>Objectives</b> (goals and concerns)</p> <ul style="list-style-type: none"> <li>• I want to find out more about my condition. <ul style="list-style-type: none"> <li>◦ <b>When can I start to do normal things again, household tasks, work, gardening?</b></li> <li>◦ <b>When will I be able to drive again?</b></li> </ul> </li> <li>• I would prefer information in both lay and medical terms.</li> </ul> <p><b>People:</b> My wife and children, my family, Patient Information Navigation Study.</p> <p><b>Evaluation</b> (consequences of each choice for each objective)</p> <ul style="list-style-type: none"> <li>• <b>What is the risk of the tumour re-growing in the same place?</b></li> <li>• <b>Are there any long-term effects from the location of the tumour or the surgery?</b></li> <li>• <b>Is this condition in any way hereditary, in terms of my children?</b></li> <li>• <b>Will my condition affect my ability to travel and get travel insurance?</b></li> <li>• <b>Other than driving and drinking alcohol, is there anything I can't do?</b></li> <li>• <b>Will all my medical information be automatically shared with my GP?</b></li> <li>• <b>What future symptoms should I look out for? Should I be concerned about a headache?</b></li> <li>• <b>What is my prognosis?</b></li> </ul> <p><b>Decisions and next steps</b> (best choice and next steps)</p> <ul style="list-style-type: none"> <li>• <b>What happens next, and who does what?</b></li> </ul>
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## **Recording and summarising**

Navigators attended the oncology clinic appointment with the patient. They met participants at reception and provided them with an additional hard copy of their consultation plan for that clinic meeting. All medical consultations were, with permission, audio-recorded. All discussions in the clinic appointment were between the patient/participant and clinician. The Navigator did not input. Navigators sat at the back of the consultation room and made notes using a laptop, of the key information relayed to the patient by the consultant and the clinician's answers to the patient's specific questions or concerns.

Once the medical consultation had concluded, Navigators used the audio recording to edit summary notes taken during the medical consultation to create a 'consultation summary' containing information communicated during the consultation. Summaries were kept concise and documented only key points discussed by the consultant with the patient. The six SCOPED categories were used to organise this information. Navigators emailed the consultation summary to the Consultant for the document to be checked for accuracy. Once any required changes were made, a consultation summary document was posted to the participant, their general practitioner and the consultant within a week of the consultation. An audio-CD copy of the medical consultation appointment was also made available to participants. This was either available immediately after the medical consultation appointment or it was posted to participants via recorded delivery. Where possible, Navigators followed the same patients through their cancer treatment, and therefore through the stages of the evaluation study.

## **Outcome**

A consultation summary and CD. An example of a consultation summary can be found in Appendix 5.

#### **4.6.4. The setting and sample**

When evaluating a complex intervention there is potential for any difference in outcome to be due to a range of factors including: the intervention itself, aspects of the healthcare systems within which the intervention is delivered, aspects of the interactions with the research process (Wells, Williams, Treweek, Coyle & Taylor, 2012). Whilst study design can attempt to mitigate against these, problems can remain when drawing conclusions about the applicability of an intervention in other healthcare settings. Oncology clinic appointments were integral to the evaluation of the Navigation intervention, and yet these were provided in diverse clinic settings with different consultants using a range of different skills and consultation processes. In noting this, every effort was made to standardise the delivery of the intervention used by Navigators in this study. The training undertaken by the Navigators is described below.

#### **Navigators**

Two Navigators delivered the intervention across both patient populations. Both Navigators were research psychologists. One had previous training in using the Navigation intervention with prostate and breast cancer patients. The other was newly appointed. Neither had experience of Navigation within this trial's sample populations (HGG and CRC) or with repeated engagement of the intervention. Both were recruited as research assistants and neither had a medical background or were familiar with the sample population care pathways. To ensure standardisation in approaches, both were given training in Navigation and observational time was spent in the respective oncology out-patient clinics observing appointments to familiarise themselves with the course of clinical treatment decisions.

Navigators were trained to be supportive and non-directive (Stacey, Murray, Légaré, Dunn, Menard, & O'Connor, 2008). In order to standardise the procedures and delivery of the intervention, a protocol, manual and training programme developed by Belkora and previously used to train Navigators in a study conducted by Sepucha et al., (2000) was used. A 3-day intensive training course delivered by an experienced Navigator who was not a member of the evaluation research team, was delivered to the two Navigators in this research. This training described the theory underpinning the intervention, how to use the SCOPED question prompt sheet to elicit a patient's key questions and concerns, it used case examples to illustrate how to produce an accurate summary of the consultation using the SCOPED framework and create the consultation audio recording. Remote supervision was provided by Belkora and team from the University of California, regularly throughout the study to both Navigators to ensure the quality of the intervention was maintained. Although supervision was often conducted in pairs the option to engage in individual supervision was always made available. During supervision, cases were discussed anonymously and constructive feedback provided on consultation planning techniques and the documents generated.

As it was likely that the Navigators' role would expose them to sensitive and emotionally charged situations, Navigators faced the potential for emotional distress resultant from being present in medical consultations where patients were receiving difficult and emotionally challenging information. De-briefing sessions were therefore important for Navigators. Navigators engaged in formal monthly sessions with a clinical psychologist based in the onsite Maggie's Cancer support centre. Whilst clinical supervision provided a safe and confidential environment for Navigators to reflect on and discuss their work and is in line with current best practice (Care Quality Commission, 2013), the provision of clinical

supervision when using decision support interventions has not been previously reported. In addition, time was also set aside fortnightly for informal team de-briefing sessions.

### **Oncology clinicians**

Oncology clinicians were not trained in any aspect of Navigation but were involved in the planning stages of the trial evaluation. Clinicians were made aware of the evaluation plan and the intervention, highlighting specifically the ways in which it would impact their provision of usual care i.e. a consultation plan to attend to, an audio-recorder in the room. The study was conducted in the same clinic as a previous RCT evaluation of Navigation (Hacking et al.'s 2013) and so all clinicians were familiar with the intervention. Prior to (usually the day before) each Navigated clinic appointment, clinicians were emailed a participant's consultation plan. Clinicians were aware that participants would then have the consultation recorded, that a Navigator would be attending the appointment, and that a consultation summary would be produced. Clinicians were encouraged to review their patient's consultation plan prior to beginning the appointment. Verbal or written (via email) agreement for recording consultations and for the Navigator to attend the appointment was taken from each clinician prior to each appointment.

### **Clinical Nurse Specialists (CNS)**

Throughout the trial it became apparent that the CNS attached to the cancer specific out-patient clinics would benefit from a copy of the consultation plan and therefore these were provided. The impact of this was not evaluated as it was a practice that evolved during the study in the interest of patient care.

## **General Practitioners (GP)**

With participant consent, the patient's GP was notified about the study and for the intervention group, the patient's GP received all the participants' oncology consultation summaries.

## **Research Team**

The research team included five members. One member, the author of the thesis, was active in recruitment and data collection. Two were trained as Navigators and as such did not take part in any data collection. One member was a consultant clinical psychologist and could provide guidance for working effectively with the clinics. Another was a senior research member able to provide methodological advice.

### **4.6.5. The Navigated patient pathway and evaluation protocol**

Important in this evaluation was to identify key appointments within the CRC and HGG treatment pathways where consultations involved the information sharing of significant clinical updates and where significant questions and decision-making about treatment direction were to be made. These were identified as the most relevant and significant consultations to be used in evaluating the intervention. All such appointments were to be during the participant's first line treatment for cancer: spanning a time period of approximately six months.

To identify the key consultations points informal discussions were held with consulting clinicians, clinical nurse specialists and a focus group held with a small cohort of patients from each population (n=9) accessed through charities (the results of the focus groups will

not be reported here). Across the CRC and HGG patient treatments, key discussions were identified that were held with oncology consultants about patient treatments.

Two flowcharts are below map the medical consultation for each population, and as outlined in the TIDieR checklist, these are important diagrammatic methods that depict the nature and chronology of the intervention (Perera, Heneghan & Yudkin, 2007; Hooper, Froud, Bremner, Perera, & Eldridge, 2013). The medical consultations highlighted in blue in Figure 2 and 3 were defined as the ‘key appointments’. The next sections describe these appointments in more detail. For each key appointment, an intervention participant engaged in the process described earlier i.e. Navigation consultation planning, and provision of a summary and CD.

#### **4.6.5.1. Colorectal cancer (CRC) appointments and evaluation time points in detail**

Colorectal cancer participants were randomised to receive the Navigation intervention or usual care. After each key appointment, all CRC trial participants were sent a battery of outcome measures, described in Chapter 5, to evaluate their experiences, annotated in Figure 2. These were sent to all participants once all Navigated materials (Summary and CD) had been distributed. Outcome measures were taken at five time points (with an additional time point for Navigated participants). Qualitative evaluation through use of interviews occurred after treatment had ended with a sample of participants recruited and interviewed from both trial arms i.e. Navigated and control groups who had completed three consultations.

The number of appointments each participant attended varied according to their needs and treatment pathways. The minimum was one (if treatment was not accepted) and the maximum was four (if more time was needed to deliberate about treatment). It was decided that the intervention would be applied to all the appointments required by a participant during the first line of their treatment. Regardless of the number of appointments/Navigations, all

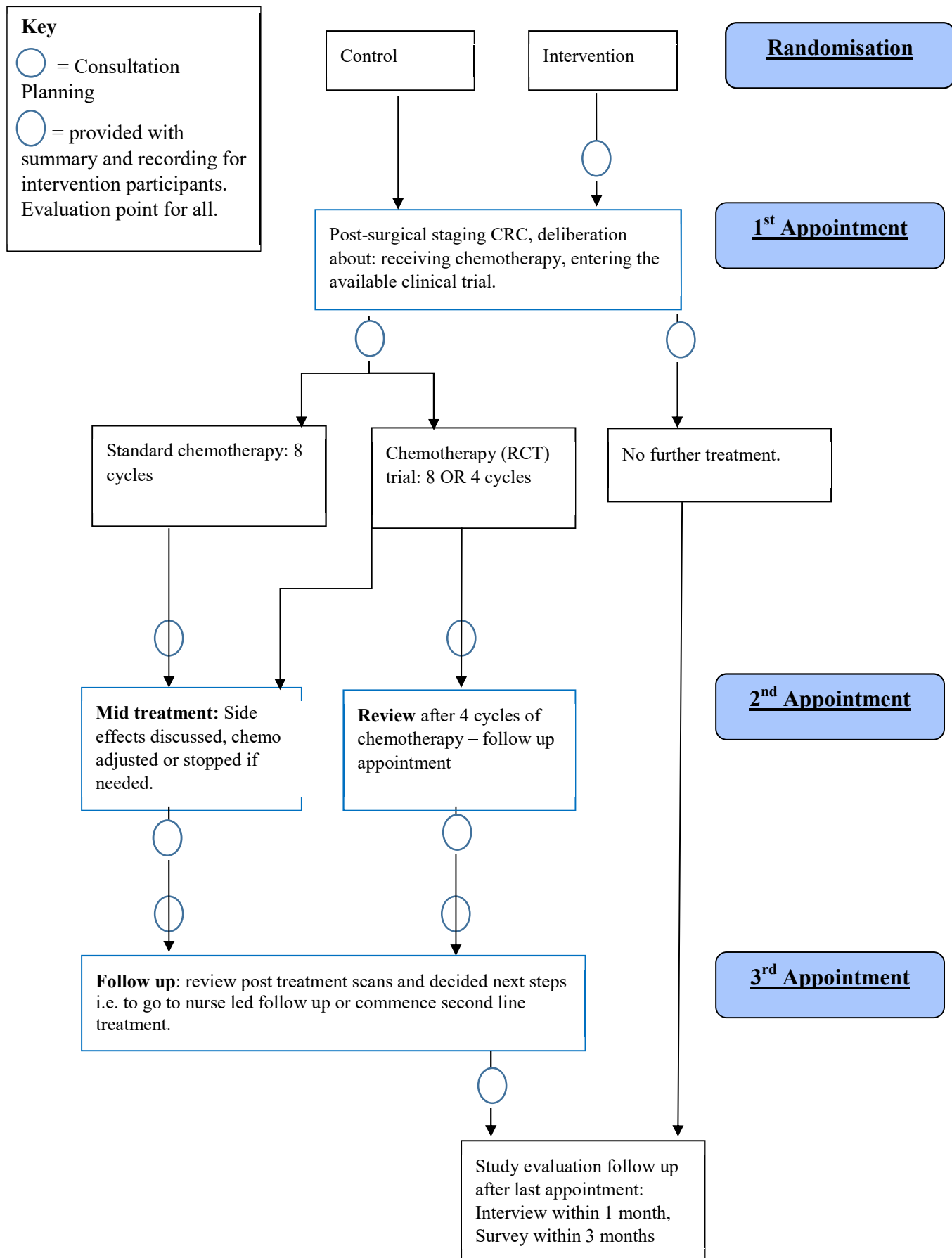
participants were sent outcome measures evaluating their experiences of care three months after their final clinic appointment as shown in Figure 4.3.

Appointment 1: This was the initial oncology consultation in clinic where chemotherapy was discussed following the results of bowel surgery. Discussions with the patient included; formal diagnosis from the pathology of tissue/tumour removed during surgery, treatment options with provision of information about side effects, and the availability of clinical trials. Next line treatment included eight weeks of chemotherapy. Due to a concurrently running clinical trial (SCOT trial) patients could have either eight or four cycles of chemotherapy. Some participants needed two initial appointments to finalise their treatment decision.

Appointment 2: This occurred three months after the initial appointment. For patients receiving eight cycles of chemotherapy this was a mid-treatment appointment, where side effects of treatments were discussed and chemotherapy adjusted / discontinued if necessary. For patients receiving four cycles of chemotherapy this was an end of treatment review, as described in appointment 3.

Appointment 3: This was six months after the initial appointment. This appointment was an end of treatment review for those who had received eight cycles of chemotherapy. It reviewed post staging scans, discussed management of any lingering treatment side effect symptoms and decided next steps i.e. to go to nurse led follow up or to commence second line treatment.

**Figure 4.3** *Colorectal cancer treatment pathway. Flowchart to present the treatment pathway, intervention and evaluation points for patients with CRC.*





#### **4.6.5.2. High Grade Glioma (HGG) appointments and evaluation time points**

As previously presented, the CRC cohort were involved in both the RCT and the nested qualitative evaluation study. However, a HGG cohort was also Navigated and interviewed as part of the qualitative evaluation. Details of this cohort's evaluation time points are now described.

All HGG patients who were diagnosed during the time that this study was conducted were invited to take part in the intervention. No randomisation occurred due to the small sample size available and the exploratory nature of the qualitative evaluation. Whilst participants in the study engaged in three Navigated consultations from baseline to follow up, this thesis only presents analysis from the final interviews undertaken after the end of treatment. This facilitated the comparison of experiences across both CRC and HGG populations, and builds an evidence-base for understanding potential applicability of the intervention for the HGG patient cohort. Further details of the qualitative methods utilised will be described in Chapter 7.

The following paragraphs details the content of the appointments for which the intervention was utilised, as represented in Figure 3. This care pathway is similar to the CRC care pathway. The number of appointments for patients on this pathway ranged from one to four, as displayed in the Figure 4.4.

Appointment 1: This appointment was the diagnosis consultation. In contrast to the CRC care pathway for the majority of HGG participants this initial appointment informed them of their diagnosis. The first clinic appointment for HGG patients occurred at the point of diagnosis. At this appointment patients received the diagnosis of HGG following the results

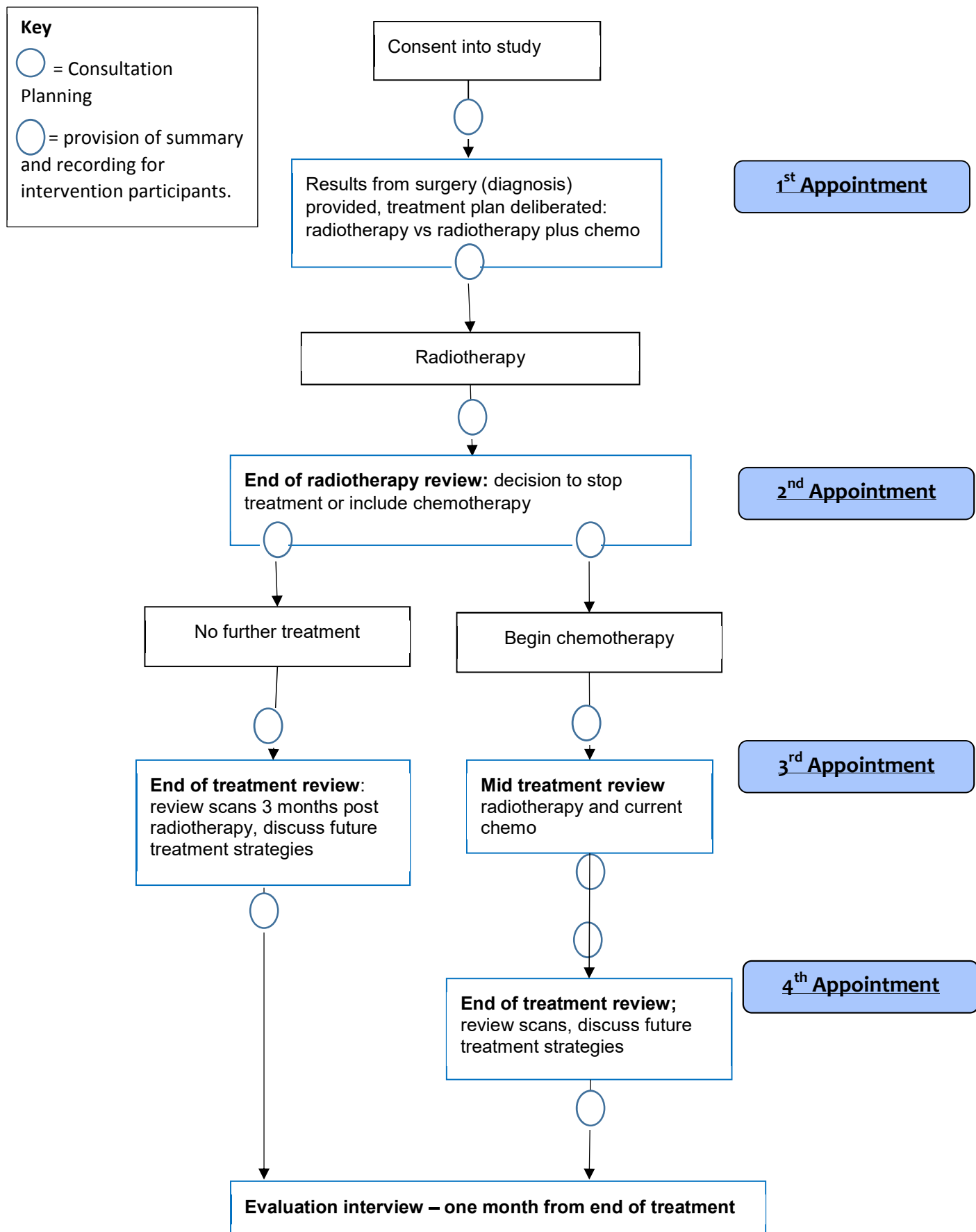
of their surgery. Within this appointment, patients were also offered treatment options of radiotherapy, plus or minus chemotherapy, and the inclusion into on-going clinical trials. Patients were expected to make treatment choices on the day and trial choices within two days. Due to the poor prognosis, it was expected patients would demonstrate a range of emotions at during this consultation.

Appointment 2: This consultation occurred after radiotherapy treatment. At this point, patients were seen by the oncologist to discuss symptoms and the possibility of adding chemotherapy into their treatment regime. As scans undertaken at this time are unable to differentiate between the tumour progression and effects of radiotherapy, no information can be given as to how well treatment is working.

Appointment 3: This occurred at a three month follow up appointment. Three months after the end of radiotherapy a patient's scan results were reviewed with the consultant oncologist and information given to the patient about either the progression, stability or a reduction in the tumour size. The result of this scan guides the next steps of treatment, if required. If participants do not require/do not elect to undertake chemotherapy, this is the end of their treatment review appointments.

Appointment 4: This appointment occurred at end of treatment as a review consultation for patients completing chemotherapy treatment. Following chemotherapy, patients attend this consultation with their consultant oncologist to discuss treatment side effects, symptom management and future disease management. This may include possible treatment options should the tumour progress in the future. Information is given for signs of disease progression, and the next CT scan is booked.

**Figure 4.4.** *HGG treatment pathway. Flowchart to present the treatment pathway for patients being treated with a High Grade Glioma.*



#### **4.7.Conclusion**

This chapter has described the study design used to evaluate Navigation, a complex intervention that aims to improve decision making in the context of the medical consultation in this case with CRC and HGG patients. In detailing the intricate Navigation procedures and data collection time points across both samples and within the RCT and nested qualitative evaluation study, the complex nature of this evaluation study has been described. Chapters 5 and 7 will provide detailed descriptions of the methods used and provide further justification for these. Chapters 6, 8 and 9 will detail the results.

## **Chapter 5: Randomised Controlled Trial with CRC patients; the methodology**

### **5.1 Introduction**

This chapter describes the Randomised Controlled Trial (RCT) conducted with colorectal cancer (CRC) participants. The chapter includes the study design, participant recruitment and consent, randomisation and blinding, outcome measures and statistical analysis. This chapter utilises the CONSORT checklist for non-pharmacological trials (Boutron et al., 2008) and pragmatic trials (Zwarenstein et al., 2008) to report the methodology and findings of the trial. This checklist can be found in Appendix 6. The study setting and a detailed description of the intervention has already been detailed in Chapter 4. Results of this RCT are reported Chapter 6.

### **5.2. Evaluating a complex intervention: utilising a pragmatic randomised controlled trial**

One of the first cited RCTs was published in the mid-1940s (Stuart-Harris, Francis & Stansfeld, 1943). The RCT is now regarded as the gold standard in clinical trial design to produce unbiased results for health care interventions (National Institute for Health and Care Excellence (NICE, 2006). In the search for reliable evidence to inform decision making, more emphasis is placed on the results of randomised controlled trials than any other form of evidence when making recommendations for healthcare (Medical Research Council (MRC) 2000). The rationale for utilising a randomised controlled trial, as guided by the MRC guidance to evaluate complex interventions has been outlined in Chapter 4, section 4.3. Consequently, this section will justify the use of a pragmatic RCT in this evaluation.

RCTs are experiments designed to achieve high internal validity, controlling where possible for most confounding variables through exclusion criteria and randomisation. However, it is this high internal validity which can ultimately result in a low external validity. The RCT design produces an evaluation under the ideal circumstances that demonstrate the best results

for the trial. Schwartz and Lellouch (1967) were the first to consider how applicable and translatable RCT results actually were to everyday practice. Accordingly, they formulated the terms ‘exploratory’ to define the traditional RCT and ‘pragmatic’ to refer to a more flexible RCT design. The exploratory RCT described trials that “aim to evaluate the efficacy of an intervention in a well-defined and controlled setting” (Patsopoulos, 2011, p.218). In contrast, the pragmatic RCT is one that “determines the effects of an intervention under the usual conditions” (Thorpe et al., 2009 p. 464). Pragmatic trials are part of the solution in the aim of producing generalizable results from RCTs. The investigation within a pragmatic trial explores “whether an intervention actually works in real life” (Patsopoulos, 2011, p218). In this way, it aims to evaluate the intervention within the usual clinical setting to capitalise the generalisability.

The distinction between an exploratory and a pragmatic trial is not binary. In reality many trials have aspects of the two designs as such the distinction between the two trials exist on a continuum (Thorpe et al., 2009). This has led to the development of a framework of domains to enable evaluation of whether a trial is pragmatic or exploratory (Gartlehner, Hansen, Nissman, Lohr, & Carey 2006, Thorpe et al., 2009). The framework by Gartlehner et al., (2006) consisted of eight domains each with a yes/no dimension to evaluate the trial. Thorpe et al., (2009) subsequently developed the PRECIS tool to distinguish between the pragmatic and explanatory trial based on ten domains. The domains are used to determine the level to which a trial is pragmatic or explanatory. Although this is an intriguing idea, the framework is difficult to apply and quantify as judgement of the domains appears subjective in nature. The PRECIS tool in contrast, uses one overarching question to define a pragmatic trial; a research question which ask ‘Does an intervention work under usual conditions?’

A pragmatic design is highly applicable to non-pharmacological trials where outcomes are based in patient-report measures of experience and not biological markers. For this trial, the evaluation of the intervention within the everyday clinic settings was integral to the nature and quality of the intervention and its evaluation. Through utilising the pragmatic trial, this trial is able to evaluate the intervention in its natural setting whilst maintaining a robust approach to the collection of data.

In questioning the validity of the RCT results, one of the areas highlighted as a weakness is that of patient preference for one trial arm (Relton, Torgerson, O’Cathain, & Nicholl 2010). The importance of recognising patient preferences for a trial arm i.e. preference to be part of the intervention or control arm, has been highlighted by Coates (2010). It can be assumed the main incentive to participate in this study (apart from altruistic reasons) is for the intervention, since the usual care is available to patients without the need to participate (Relton et al., 2010). As this intervention depends on participant involvement and co-operation, a participant’s preference for the study trial arm needs to be considered. Where a participant is allocated to the least preferable arm of the intervention they may withdraw from the trial or display disappointment bias when completing evaluation measures (Torgerson & Torgerson 2008). However, to take account of such preferences within the design of the study would not necessarily solve problems of attrition or disappointment bias (Preference Collaborative Review Group, 2008) and would compromise the robustness of the considered research design. Although it is important to acknowledge preferences, in this study participant preference was not considered and all potential candidates were made aware of this.

### **5.3. Study design**

The selected trial design is an open parallel-group pragmatic RCT. Participants were openly randomised after completion of baseline measures to receive the intervention (Navigation) or usual care (no intervention). The study is longitudinal in nature with the intervention administered three times per participant. Participants completed outcome measures prior to baseline, post each consultation (x3) and at follow up (three months following last appointment at the clinic).

#### **5.3.1. Primary Research Question**

To address the information and decision making needs of people with colorectal cancer this study asks the following question:

‘What is the effectiveness of providing a decision support intervention (Navigation) to people with colorectal cancer for their clinic appointments during first line treatment for their cancer, on improving their decision quality when compared to usual care?’

This primary research question is answered through the self-report of people with colorectal cancer, who experienced or did not experience the intervention, completing measures of Decision self-efficacy (DSE), Decision Conflict (DCS), Decision regret (DRS) and Preparation for Decision Making. The outcome consisted of changes in reported scores over time between groups.

#### **5.3.2. Secondary research question**

‘Does the intervention impact on the anxiety or depression experienced by people with colorectal cancer over the course of their treatment?’



### **5.3.3. Hypothesis**

*Null Hypothesis:* Using the intervention with people with colorectal cancer during their cancer treatment will result in no differences in the perception of decision quality between intervention and usual care groups.

*Alternative Hypothesis:* Using the intervention with people with colorectal cancer during their treatment will result in an improved perception of decision quality for the intervention group when compared to usual care.

## **5.4. Recruitment and Participants**

### **5.4.1. Eligibility criteria**

Eligible participants were adults aged 18 or over with a new diagnosis of CRC (curative or palliative), who were attending the colorectal cancer clinic, from December 2010 - March 2013 for their first oncology treatment discussion and subsequent treatment regimen. Patients with a diagnosis of colon cancer or rectal cancer were invited into the study as both followed a similar pathway of care managed by the same clinical team.

All patients considering adjuvant chemotherapy following surgery were the study population. Due to the nature of the CRC treatment pathway, this included all Stage 2, 3 and 4 patients and eliminated all stage I patients from the study population. The following exclusion criteria were applied to the recruitment selection process:

- People with a previous diagnosis, in order to minimise bias when evaluating the Navigation intervention from the perspective of first time oncology treatment decision making.
- Non-English speaking, due to lack of resources to accommodate translation.

- People with identifiable severe psychiatric morbidity or with a limited capacity to understand or engage fully with the intervention.

#### **5.4.2. Recruitment**

Eligible patients were identified at the multi-disciplinary team meeting (MDT) (see Figure 1). At this meeting, patients' surgery results were discussed and those with a higher stage of disease were invited to the cancer centre for an appointment with the oncologist to discuss further treatment (chemotherapy). Those who needed no further treatment were not eligible for the study. This first clinic appointment acted as the first Navigated appointment.

Patients were notified of their initial clinic appointment via a telephone call with the clinic's Clinical Nurse Specialist (CNS). The telephone was a standard method of contact utilised by the clinic as patients were usually at home recovering from bowel surgery (undergone 1 week prior). In this phone call the CNS would briefly explain that the upcoming appointment would be about the need for further treatment, often chemotherapy, due to the results of the surgery. The study team were notified by the CNS if a patient was eligible and when they had been made aware of their appointment.

Patients were invited to participate in the study via a separate phone call from the study team. This approach was selected following an initial poor recruitment rate when the CNS made the initial recruitment approach. Specific ethical approval was given to approach the patients without first being introduced by a member of the patient's healthcare team.

In the recruitment telephone call made by the study team, a description of the study was provided and permission was sought to post a study pack to the potential participant, and then to establish contact via the telephone again 48 hours later. Those who declined participation

in the study were thanked. No further contact was made. The study pack (Appendix 7, 8 & 9) included: invitation letter, information sheet, consent form (one for participants to keep and one to return to the study files), the baseline questionnaire (including three measures described below) and a stamped addressed envelope. The follow up phone call ensured participants had received their study pack, gave opportunity to provide more detail about the study, and answer any questions about the study. At the end of the follow-up telephone call participants were asked if they would like to take part in the study, or not. Again, those who declined were thanked and no further contact was made. Reasons for refusal were not requested although some information about this was volunteered and examples of these are presented in Chapter 6.

Participants who agreed to take part in the study were verbally taken through the consent form items over the telephone: this verbal consent was audio recorded. Participants were also asked to complete and sign the consent form and asked to bring it back to clinic or return in the post using the stamped addressed envelope. In order to undertake randomisation participants were then requested to complete their baseline questionnaire and post this back in the stamped addressed envelope provided as this was the most time efficient method.

The time between initial study contact and clinic appointment was one week giving time for participants to complete the recruitment and consent process, complete baseline measures and for intervention participants to take part in their consultation planning appointment as described in Chapter 4, section 4.6.3. Consequently, it was impractical within the timeframe to wait to receive a participant's baseline measures via post before informing them of their allocated group. For this reason the study relied on a participants' verbal assurance that baseline measures were complete, and provided an agreed amount of time to ensure this.

Participants were then randomised and informed which group they had been allocated to (Intervention or Control).

The numbers of eligible and consented participants are represented in the CONSORT flow chart in Chapter 6.

### **Control group**

Participants in the control group were informed via telephone conversation before their clinic appointment that they would not be receiving the Navigation intervention. This group of participants completed five separate questionnaire packs over nine months: baseline, after each of three key clinic appointments (initial, mid-treatment and end of treatment) and three months following the last appointment. Every set of questionnaire included a stamped addressed envelope for participants to return their completed measures.

A weakness often discussed with regards to RCTs is that information about standard care is seldom given for the control group (Hoffman et al., 2014). The usual care for patients in this control arm was usual care provided by this clinic. This is a morning clinic where consultants and registrars meet with people diagnosed with colorectal cancer to plan or review their treatment. Clinical Nurse Specialists (CNS) are available for support but do not provide formal appointments within this clinic time. This trial arm received no input from the study with regards to their appointments at the clinic. Communication between the study and control participant was limited to questions about and delivery of questionnaires and interview invitations and arrangements.

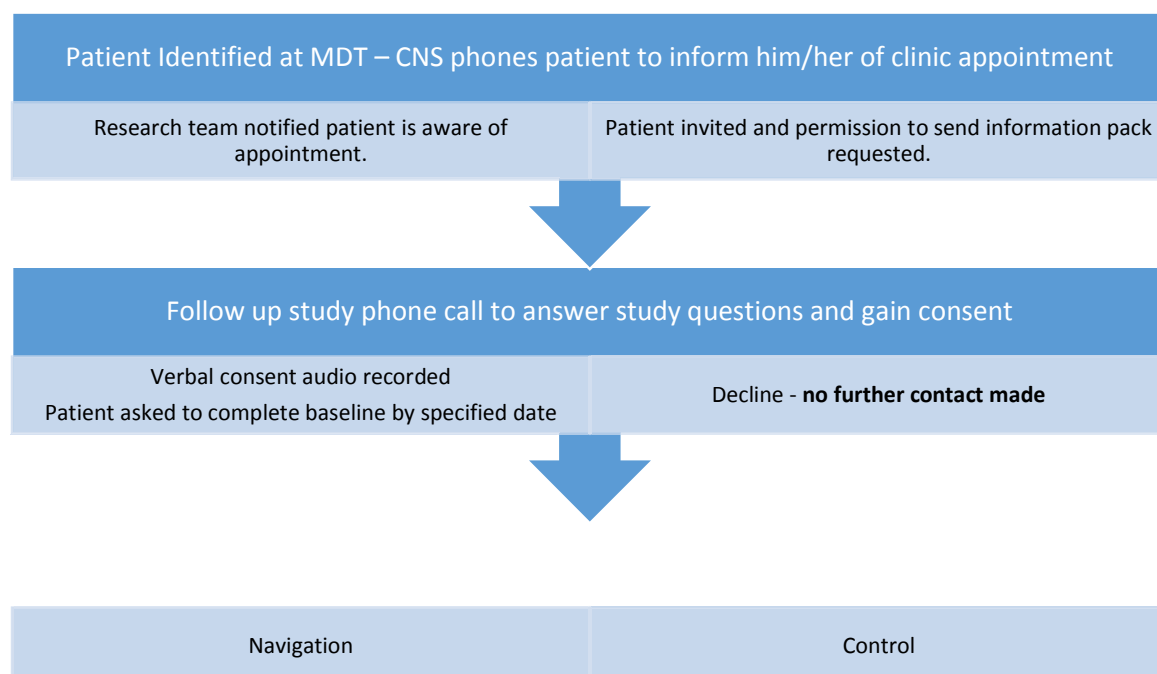
## Intervention Group

Participants who consented to participate in the study and who were randomised into the intervention group, i.e. receiving the Navigation intervention were contacted by the Navigator at an arranged time for their initial consultation planning appointment. Participants were ‘Navigated’ for 3 appointments: initial oncology treatment consultation, mid treatment consultation and end of treatment consultation. This occurred over a six month period.

The intervention arm completed the same five separate questionnaire packs over nine months as the control arm. In addition, the intervention group completed one extra measure after their baseline measure and prior to their clinic consultation.

A flow chart of the appointments attended and evaluation points taken can be seen in Chapter 4, Figure 5.1.

**Figure 5.1.** *Recruitment and Consent Procedure. Flowchart to present the consent and recruitment procedure for patients with colorectal cancer.*



## **5.5. Outcome Measures**

The outcome measures were informed by the Ottawa Decision Support Framework (OTDSF) (O'Connor et al., 1998), detailed in Chapter 4, section 4.6.2., in conjunction with the specific goals of the Navigation intervention to; encourage confidence and reduce confusion and regret in decisions that have been made (Belkora et al., 2008). As proposed by the OTDSF, decision support interventions should measure indicators of quality decision making as opposed to the outcome of the decision, as it is suggested good decision making can still result in bad outcomes, particularly in the uncertain context of cancer (O'Connor et al., 1998). The authors suggest these indicators include such things as; knowledge, clear values, expectations, low decision conflict, decision implementation and satisfaction with the decision and the process of making the decision (O'Connor et al., 1998). In this study, the quality of the decision implementation was measured using the Decision Self-Efficacy Scale (DSE, O'Connor, 1995) to evaluate the personal resources a participant had to implement the decisions. Satisfaction with the outcome of the decision was measured using the Decision Regret Scale (DRS, O'Connor, 1996) while the decision making process was measured with the Preparation for Decision Making scale (Graham & O'Connor, 1995). The Decision Conflict Scale (DCS, O'Connor, 1995) measured a participant's perception of uncertainty with the decision.

It is hypothesised based on the review of the theoretical evidence for coaching by Stacey et al. (2013) that the intervention may improve the feelings of confidence through the discussion and deliberation with another who provides support and validation Stacey et al. (2013). Furthermore the review also indicates the intervention may also improve the likelihood that the participant's emotions are considered by the clinician throughout the process, through Navigator clarification and encouragement to express them in the consultation plan. This may

result in a low feeling of decision conflict. Following Janis and Mann's (1997) conflict model of decision making the provision of information tailored to the individual through the consultation summary and record could also result in a reduced feeling of uncertainty in the decisions. Furthermore, the Ottawa framework postulates that through the identification of information and decision making needs (via in this instance the consultation planning part of the intervention) the participant is enabled to achieve higher quality decisions in turn affecting outcomes such as regret (O'Connor et al., 1998)

The DSE, DCS, and DR have been used previously to evaluate the Navigation intervention with breast (Belkora et al., 2008) and prostate cancer populations (Hacking et al., 2013). All measures used were self-administered and all are validated research instruments.

**Table.5.1.** Demonstrates the evaluation and determinant factors of the measures used according to the Ottawa decision support framework.

<b>Measure</b>	<b>Evaluation</b>	<b>Determinants</b>
DSE	Quality of decision and decision making process	Resources to make and implement decision
DCS	Quality of decision and decision making process	Perception of the decision
DRS	Outcome of decision	Perception of the decision
PfDM	Quality of decision and decision making process	Resources to make and implement decision
HADS	Outcome of decision	Reduced distress from decision making consequences.

### **5.5.1. Baseline demographics**

Basic demographics (Appendix 10) taken included; age (self-reported on a continuous scale); gender (male or female) ethnicity (White, Mixed ethnicity, Asian or Asian British, Black or Black British, Other), marital status (Married, Divorced, Separated, Widowed, Single) educational background (Left before 15, Secondary education to 16, Secondary education to 18, College, University, Other) and employment status (working full time, working part time, retired, unemployed, other).

### **5.5.2. Primary Outcome Measure**

#### **5.5.2.1. Decision Self Efficacy (DSE) (O’Conner, 1995).**

The primary outcome measure was decision self-efficacy (Appendix 11). This scale was used to measure a participant’s perception of their personal resources (confidence) needed to implement a decision. The Decision Self Efficacy (DSE) is an 11 item scale which measures self-confidence or beliefs in one’s personal abilities in decision making, including shared decision making. This scale has been shown to demonstrate high internal consistency (Cronbach’s  $\alpha = 0.92$ ) (O’Connor 1995). Perceiving oneself as able to influence events meets a core principle of shared decision making. The DSE has been used to evaluate the Navigation intervention before and was found to be sensitive to this intervention (Belkora et al., 2008). Belkora et al. (2008) found although participants ( $n=38$ ) reported a relatively high baseline of decision self-efficacy meaning limited room for improvement at, the standardised effect size for the scale was large at 0.85, indicating this scale may be responsive to the impact of the intervention.

To measure a participant’s belief in their abilities to make decisions this measure was taken at baseline (T1) and after each consultation (T3, T4, & T5). In addition, intervention



participants completed DSE after their consultation planning appointment with the Navigator and prior to the clinic appointment (T2) to measure any change in DSE attributable to the consultation planning part of the intervention. Control participants did not complete this measure at this point as the baseline measure of DSE was taken a minimum of five days prior and it could be assumed there was no reason for this score to have changed. DSE was not measured at follow up as it has been suggested that the validity of this measure weakens as time away from the consultation increases. A measure of personal resources three months after the event (the consultation) may not be reflective of the experience at the time.

Participants were asked to report on a scale of 0 – 4 (0 not at all confident to 4 very confident): ‘I feel confident that I can...’ in response to eleven items. To create a total score per respondent all 11 items were summed, divided by 11 and multiplied by 25, therefore total scores for DSE ranged from 0 (not at all confident) -100 (very confident).

### **5.5.3. Secondary outcome Measures**

#### **5.5.3.1. Decision Conflict Scale (DCS, O’Connor, 1995).**

To measure uncertainty in decision making the Decision Conflict Scale (DCS) (Appendix 12) was selected (O’Conner, 1995). Decision conflict is defined as an emotional state involving the feeling of uncertainty when choosing between options (O’Connor, 1995), and is known to commonly occur within the context of health decisions. This 16 item scale measured personal perceptions of uncertainty in choosing options, modifiable factors contributing to uncertainty such as feeling uninformed, unclear about personal values and unsupported in decision making, and effective decision making, such as feeling the choice is informed, values based, likely to be implemented and expressing satisfaction with the choice (O’Conner, 1993). Internal consistency coefficient exceeded 0.78 (O’Connor, 1995).

The DCS was administered after each consultation (T3, T4, & T5) and at three month follow up (T6). Respondents were directed to think about a choice they had made and rate how strongly they agreed to or disagreed with the 16 statements. Decision conflict rating was completed immediately after each consultation to evaluate recent decisions made in the consultation.

Responses to each statement were rated from one (strongly agree) to five (strongly disagree). Total scores were summed and divided by the number of items. A total score of 1 indicated a participant had reported low decisional conflict where five indicated a high level of decision conflict (O'Connor, 1993).

#### **5.5.3.2. Decision Regret Scale (DRS, O'Connor, 1996).**

To measure the regret a participant experienced in regard to their treatment decision, the Decision Regret Scale (DRS) (Appendix 13) was selected (O'Connor, 1996). This is a 5 item self-administered scale that measures “distress or remorse after a health care decision” (Brehaut et al., 1996, p283). A low regret score indicates positive feelings about the decision made. This measure has good internal consistency (Cronbachs alpha 0.81 - 0.92) (O'Connor, 1996).

The decision regret scale (DRS) was administered once at follow up (T6), so that participants could reflect on the treatment decision and its subsequent effects (O'Connor, 1996). Follow up was 3 months after a participant had been discharged from the clinic following either; the decision to not have treatment, ending treatment earlier than standard guidelines suggest (6 cycles), or at the end of full (6 cycles) treatment review

The DRS measure asked respondents to reflect on the treatment decision and rate their agreement on a scale of 1-5, on a scale anchored at 1 ‘strongly agree’ and 5 ‘strongly disagree.’ Items 2 and 4 were reverse coded so that for each item a higher number indicated more regret. Item scores were converted to a 0-100 scale by subtracting 1 and multiplying by 25. Total scores were obtained by summing each item and averaging. A score of 0 indicated no regret, a score of 100 indicated high regret.

#### **5.5.3.3. Preparation for Decision Making (O’Connor, 1995).**

To measure preparedness to make a decision four of the ten items were taken from the Preparation for Decision Making (O’Connor, 1995), (Appendix 14). These items were selected pragmatically as they have been used in the evaluation of the intervention previously and so this facilitates comparison (Sepucha et al., 2002; Belkora et al., 2015). It was acknowledged the battery of surveys over several different time points was quite a large demand on participants as such the use of only four of the ten items helped to reduce the participant burden. The four items were chosen based on the most relevant items to assess the components of the intervention, the six items not used asked about preparation for; recognising a decision needs to be made, making a better decision, thinking of the pros and cons and then which are most important to you, know the decision depends on what matters most to you, an, follow up visits. The selected items are presented in table 5.2 Using single items from the Preparation for Decision Making scale has been used in this way in other studies (Winterbottom et al., 2015). Validation studies found this scale was sensitive to decision support interventions (Pitkethly, MacGillivray & Ryan, 2008). Validation studies found high scores for internal consistency (Cronbach’s  $\alpha=92.94$ ) (Graham & O’Connor, 1996).

The Preparation for Decision Making scale was administered after each consultation (T3, T4, & T5). Respondents were asked ‘did the services in the run up to your appointment help you to...’ for the four items. Respondents rated their agreement from 1-5, on a scale anchored at 1 ‘a great deal’ and 5 ‘not at all.’

**Table 5.2.** Items measuring preparation for consultation

Did the services in the run up to your appointment...
Help you organise your own thoughts about the decision?
Help you identify the questions you want to ask your doctor?
Help you think about how involved you want to be in this decision?
Prepare you to talk to your doctor about what matters most to you?

#### **5.5.3.4. Satisfaction with the intervention**

Intervention participants were asked to rate their satisfaction of the consultation planning stage of the intervention using the question ‘Please indicate how satisfied you are with the question-listing support you received’ anchored on a scale of one not at all satisfied to ten extremely satisfied. This was administrated after each consultation T3, T4 and T5.

#### **5.5.3.5. Hospital Anxiety and Depression Scale (HADS, Zigmund & Snaith, 1983)**

The Hospital Anxiety and Depression Scale (HADS, Zigmund & Snaith, 1983) (Appendix 15) is a 14 item scale which provides separate brief state scores of anxiety (seven items) and depression (seven items). In a systematic review of screening for emotional distress in cancer patients, ten studies showed the HADS demonstrated adequate internal consistency for each subscale (anxiety or depression) and was sensitive to change (Vodermaier, Linden & Siu, 2009). When tested with a colorectal cancer patient sample following diagnosis, the HADS

was shown to be sensitive in its detection of a clinical disorder of anxiety or depression, furthermore it was deemed more sensitive in this detection than the single item Distress Thermometer (Patel et al., 2010).

In this RCT, the HADS was administered twice, once at baseline (T1) and again at follow up (T6). These time points were considered pragmatic to capture a patient's anxiety and depression at the point of diagnosis and end of treatment/ three months following the decision to not have treatment. Each item is scored on a four point scale (0-3). A total score of eight to 10 indicates a borderline state of anxiety or depression, where above 10 indicates 'caseness' (Zigmond & Snaith, 1983; Patel, Sharpe, Thewes, Bell & Clarke, 2010). It takes approximately 2-5 minutes to complete.

## **5.6. Procedure**

Data was collected at six time points. Table 5.3 demonstrates which measures were completed at each time point. The time points for measurement included: baseline (T1) which was pre randomisation, after each consultation T3, T4, & T5, and 3 month follow up after discharge from the clinic (T6). In addition intervention participants completed the Decision self-efficacy (DSE) measure post consultation planning prior to consultation (T2). Once the Navigation materials (consultation summary and CD) had been sent all participants were sent their outcome measures via post.

The evaluation was longitudinal. Participants would complete three clinic appointments and evaluation would be taken after each one was attended (as discussed in Chapter 4); the initial consultation to plan treatment, a mid treatment review appointment and end of treatment review consultation. As highlighted, participants could attend a minimum of one appointment

and a maximum of four. This impacted the evaluation time points. Where a participant had two appointments for one time point (e.g. two initial appointments to decide treatment) they completed measures after the second appointment. Final evaluation (T6) was taken three months following a participant's discharge from the clinic (from first line chemotherapy). The amount of appointments attended was recorded for each participant.

**Table 5.3** Timeline of evaluation to demonstrate the time points of outcome measures for colorectal participants.

	Timeline	Navigation	Control
T1	Prior to consultation (baseline)	Demographics, HADs, DSE	
Randomisation occurs			
T2	Post Consultation planning, pre consultation	DSE	
T3	Post initial consultation	DSE, DCS, PfDM	DSE, DCS, PfDM
T4	Post mid treatment consultation	DSE, DCS, PfDM	DSE, DCS, PfDM
T5	Post end of treatment consultation	DSE, DCS, PfDM	DSE, DCS, PfDM
T6	3 months after discharge from the clinic (follow up)	HADS, DCS, DR	HADS, DCS, DR

## 5.7. Sample Size

A power calculation was conducted using the primary measure DSE and based on a previously undertaken feasibility RCT Navigation study with prostate cancer patients (Hacking et al., 2013). The Hacking et al., (2013) study measured DSE at three time points, baseline, post first consultation and 6 month follow up. This study measured DSE at five times points and so expected and planned for a higher attrition rate. For a significance level of  $\alpha=0.05$ , to achieve power of 80% and detect a clinical difference with an average difference of 6 points (Hacking et al., 2013) between the control and intervention groups in

the primary outcome measure (DSE), 54 subjects per group at each measurement time point was required (n=108). An attrition rate of 21.14% was estimated therefore a sample size of 132 participants, 66 participants per group, was needed.

## **5.8. Randomisation and Blinding**

Participants were randomised using a web-based Randomisation Tool:

(<http://www.healthbehaviourresearch.co.uk/research.aspx> - no longer in use 23/03/16).

Simple randomisation was used.

A participant's study number was inputted into the web tool which auto generated a group number allocation for the participant; '1' (Intervention) or '2' (Control), in a random sequence.

Blinding of the participants and clinicians and during the analysis was not feasible within this study. Patients who did not accept their group allocation were not able to proceed with the study. A record of study withdrawals was recorded (see Chapter 6, CONSORT flow chart).

## **5.9. Monitoring non completers**

If a participant did not return their questionnaire they were sent a reminder, along with the same questionnaire two weeks later. If they failed to respond they were considered a non-completer. Non-completion of questionnaires was not considered as withdrawal from the study. Participants remained part of the study but the time point questionnaire was marked non-completed. Some participants did not medically require all three oncology appointments according to treatment decisions. In this instance participants did not receive the subsequent measures but were asked to complete the follow up surveys three months after their discharge from the clinic.

## **5.10. Withdrawal of participants**

Participants were free to withdraw at any time. The researcher was also able to withdraw a participant if it was in their best interest or they were no longer eligible, for example, spread of disease resulting in hospitalisation and referral to palliative care. When a participant withdrew it was recorded. All previous data were kept unless requested by the participant that they be removed, as detailed in the information sheet. No reasons were requested for withdrawal.

### **5.11. Statistical analysis**

Data were analysed using SPSS®, Version 22.0. Statistical significance was set at 0.05 and nonparametric tests were conducted if normal distribution assumptions were not met. Where data were missing due to participants not completing questionnaires no substituted data were inputted. Missing data per item response was coded as 99. Where a participant took part in two of the same consultations, (for example two initial consultations to decide treatment) they completed their survey after the final consultation.

An intention to treat (ITT) analysis was also performed on all participants regardless of the number of appointments attended, to ensure the evaluation does not over or under estimate the interventions' effectiveness. Missing data were replaced by carrying the last observation forward. This ITT analysis is detailed in appendix 16.

#### **5.11.1. Characteristic between groups at baseline**

Baseline between group (control vs. intervention) differences in age, DSE scores and HADs were compared using an independent samples t-test. Where data did not meet the assumptions of normal distribution a Mann Whitney U test was conducted. Differences in the other



measurements: ethnicity, employment status, education, gender and marital status, were tested using chi-squared as data gathered was categorical.

### **5.11.2. Primary Outcome Measure: Decision Self Efficacy**

Means and standard deviations of the whole data set were calculated. DSE scores over time (T1, T3, T4, and T5) per trial arm (intervention and control) were analysed using a mixed ANOVA. Another mixed ANOVA was run to analyse scores across T1-T3 between groups, as at this time point the main treatment decision was made, this is also comparable with other current studies of the intervention (Hacking et al., 2013). Bonferroni adjustments were used throughout to correct for multiple testing. The intervention only arm (for pragmatic reasons) completed the DSE at an additional time points, post consultation planning and immediately prior to the initial consultation (T2). A paired *t*-test was conducted to compare the difference in scores from baseline (T1) to T2 for the intervention participants, to measure the effect of the intervention (consultation planning) before the clinic appointment.

### **5.11.3. Secondary Outcome Measures**

**Decision Conflict scale:** A mixed ANOVA was used to measure the interaction between time and trial arm on the DCS measure. Bonferroni adjustments were used throughout to correct for multiple testing. Independent *t*-tests were ran to compare differences between scores at each time point (T3-T6).

**Decision Regret Scale:** An independent *t*-test was conducted to compare scores between groups. As this measure was based on expectations for treatment it was considered the number of appointments each respondent attended could be a factor in the DRS score. As such the relationship between DRS score and number of appointment was conducted via correlation testing.

**Preparation for Decision Making scale:** This scale consisted of 4 separate items. An independent t-test was conducted at each time point (T3, T4 and T5) between groups (Intervention and control). Descriptive statistics were used to examine satisfaction with the intervention from intervention only participants. Where data did not meet the assumptions of normal distribution a Mann Whitney U test was conducted. Scores were reported by participants using the scale: A great deal 1-2-3-4-5 Not at all, however for the purposes of analysis scores were flipped to reflect a more logic progression: Not at all 1-2-3-4-5 A great deal

**Hospital Anxiety and Depression scale:** A mixed ANOVA was used to measure the interaction between time and trial arm on each subscale HADS-A and HADS-D. Bonferroni adjustments were used throughout to correct for multiple testing. Descriptive statistics were calculated to summarise the prevalence of borderline and clinical presentations of anxiety and depression, from baseline to follow up.

## **5.12. Summary of methods**

This chapter has described the trial design to test the Navigation intervention within a population of participants with colorectal cancer. The challenges of evaluating a complex intervention within a clinical setting with a population of people potentially experiencing acute distress were acknowledged and a pragmatic RCT design was considered the most valid approach. The evaluation of this study is supported by the framework for evaluating decision support interventions. The next chapter reports the results of the RCT.

## Chapter 6: Randomised controlled trial with CRC patients; the Results.

### 6.1. Introduction

The previous chapter detailed the methodology utilised in this RCT. This chapter will present the randomised controlled trial (RCT) results with colorectal cancer (CRC) participants. This chapter reports on differences in outcome measures between the control and intervention trial arms over time. All *p* values are reported as actual values, where SPSS noted  $p=0.000$  this is reported as  $p<0.001$ .

This chapter begins by outlining the trial numbers for a participant's enrolment, intervention allocation, follow-up, and data analysis. Baseline characteristics of each trial arm (control and intervention) and any differences between the groups are then presented. This is followed by the results of each outcome measure. The chapter concludes with a summary of the results. The table below (6.1) serves as a reminder for the administered time points of measurement.

#### 6.1 Time points of measurement in the trial

Code	Description
T1	Baseline prior to randomisation.
T2	For intervention participants only: Post intervention (consultation planning) prior to oncology consultation – this measure was taken in clinic waiting room.
T3	Post consultation once all summary items have been distributed (within one week).
T4	Post second clinic consultation (mid treatment review for most).
T5	Post end of treatment review appointment.
T6	Three months after discharge from the clinic.

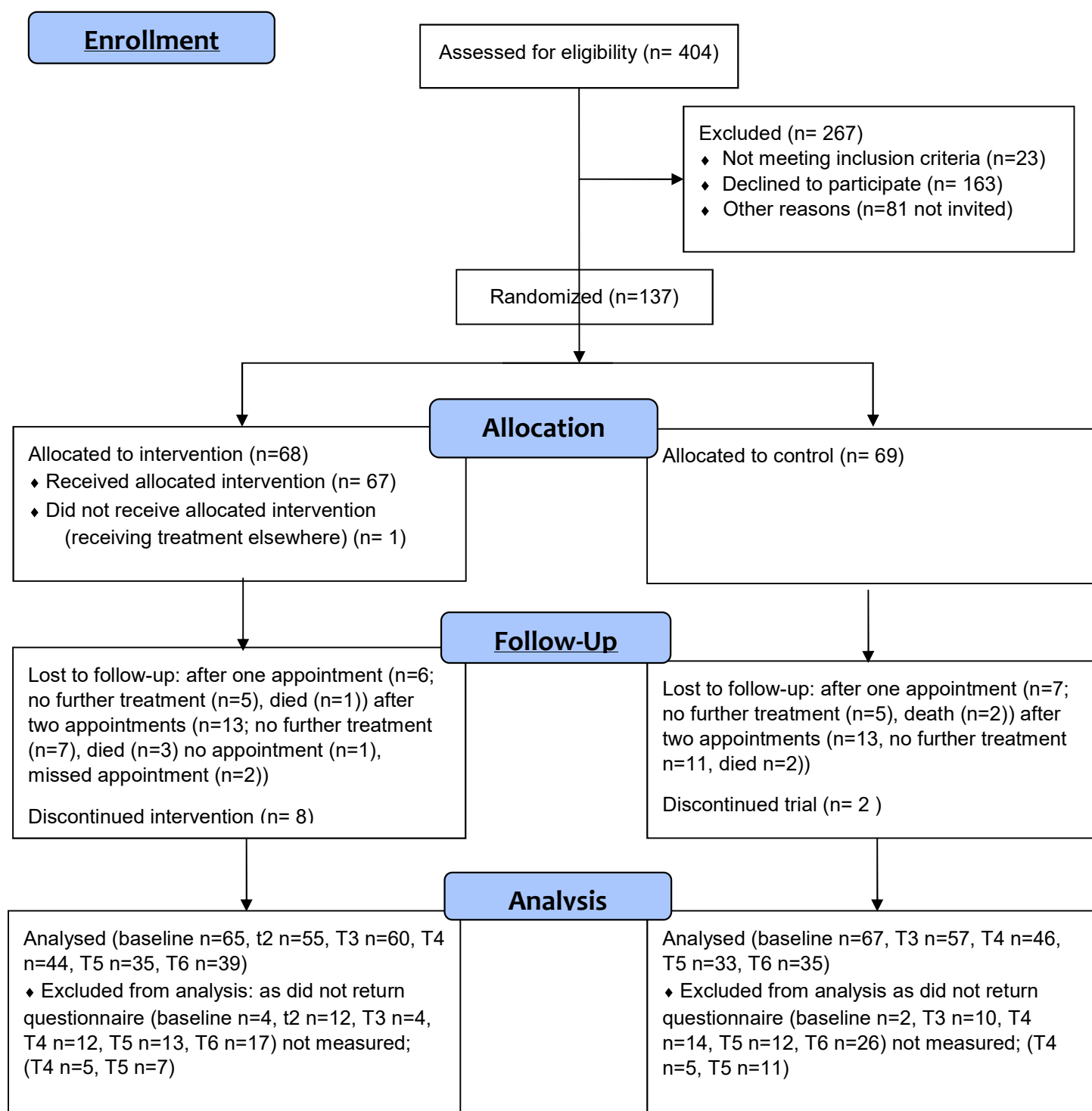
## **6.2. Sample**

404 participants were assessed for eligibility and 300 were invited into the trial. 137 accepted the invitation and consented into the study; a recruitment rate of 33.9%. At randomisation 68 participants were allocated to the intervention group and 69 to control. Subsequently one intervention participant was withdrawn as ineligible prior to receiving the intervention.

The expected attrition rate used in the original power calculation, estimated from previous research (Hacking et al., 2013) was 21.14%. The actual rate of attrition at follow up was 44.52% at T6. Figure 6.1 shows the CONSORT flow diagram (Moher, Schulz & Altman, 2001) of the enrolment, intervention allocation, follow-up, and data analysis of the trial.

Some examples of reasons provided for decline into the study were collected and included participants feeling as though they; did not have enough information about their health care situation, would like to join but only after the initial appointment was over, want to have treatment and get life back on track.

**Figure 6.1.** CONSORT flow diagram of enrolment, intervention allocation, follow-up, and data analysis.



### 6.2.1. Characteristics of participants at baseline

No significant differences were found in the baseline characteristics between groups. These are discussed below and presented in table 6.4.

The overall age range of the participants was 35 – 92, with a mean age of 62.13 (*SD*11.66). Intervention participants had an age range of 35 – 80 years, resulting in a mean age of 62.71 (*SD*11.35). Control participants had an age range of 36 – 92 years resulting in a mean age of 61.57 (*SD*11.99). No significant difference was found between when the mean age of the two trial arms were compared ( $t=0.56$ ,  $df=130$ ,  $p=0.58$ ).

The sample comprised 78 (59.1%) males and 54 (40.9%) females. In the intervention arm there were 35 males and 30 females and the control arm comprised 43 males and 24 females, a non-significant difference was found between groups ( $X^2= 1.46$ ,  $df=1$ ,  $p=0.227$ ).

Participants' ethnicity reflected the area characteristics of Edinburgh with the majority reporting to be white ( $n=129$ , 97.7%) and no difference between groups was found ( $X^2= 2.98$ ,  $df=3$ ,  $p=0.395$ ). The majority of participants were married ( $n=92$ , 69.7%) and no differences in the marital status of the groups participants was found ( $X^2= 2.943$ ,  $df=4$ ,  $p=0.567$ ).

Participants education level was variable, a minimal number of participants left school before the age of 15 ( $n=12$ , 9.16%), no difference was found between the groups education level ( $X^2= 5.65$ ,  $df=5$ ,  $p=0.342$ ). Most participants in the sample had retired ( $n=69$ , 52.67%) and again no differences between groups occurred ( $X^2= 1.01$ ,  $df=4$ ,  $p=0.908$ ).

At baseline prior to randomisation between group scores on the primary outcome measure of decision self-efficacy (DSE) were not significantly different between control ( $M79.83$ ,

*SD*20.09) and intervention participants (*M*84.24, *SD*13.29) ( $U=1795.00$   $N_1=62$ ,  $N_2=64$ ,  $p=0.36$ ).

Baseline scores of anxiety were lower in the control (*M*6.41, *SD*4.21) compared with the intervention group (*M*7.03 *SD*0.54) and scores of depression were lower in the control group (*M*4.98, *SD*3.84) compared with the intervention group (*M*5.17, *SD*3.80). When baseline scores were compared between groups no significant difference of mean scores occurred at for anxiety ( $t(127)=-0.76$ ,  $p=0.45$ ) or depression ( $t(126)=0.28$ ,  $p=0.78$ ).

**Table 6.2 Baseline characteristics of the study participants**

	<i>Trial arm at Baseline</i>		
	<b>Control (n=67)</b>	<b>Intervention (n=65)</b>	<b>p value</b>
<b>Age (yrs)</b> <b>[mean (SD)]</b>	61.57 (SD11.99)	62.71 (SD11.35)	0.417
<b>Gender</b>			0.227
Male / Female	43 (62.7%) / 24 (35.8%)	35 (53.8%) / 30 (42.6%)	
<b>Ethnicity</b>			0.395
White	64	65	
Chinese	1	0	
Mixed	1	0	
Other	1	0	
<b>Marital status</b>			0.567
Married	49 (73.1%)	43 (66.2%)	
Divorced	7 (10.4%)	11 (16.9%)	
Separated	1 (1.5%)	2 (3.1%)	
Widowed	2 (3.0%)	4 (6.2%)	
Single	8 (11.9%)	5 (7.7%)	
<b>Level of education</b>			0.342
Left before 15	5 (7.5%)	7 (10.8%)	
Secondary ed to 16	29 (43.4%)	16 (24.6%)	
Secondary ed to 18	3 (4.5%)	5 (7.7%)	
College	10 (14.9%)	13 (20.0%)	
University	18 (26.9%)	22 (33.8%)	
Other	2 (3.0%)	1 (1.5%)	
Missing	0	1 (1.5%)	
<b>Current employment status</b>			0.908
Working full time	19 (28.4%)	20 (30.8%)	
Working part time	10 (14.9%)	6 (9.2%)	
Retired	34 (50.7%)	35 (53.8%)	
Unemployed	3 (4.5%)	3 (3.0%)	
Other	1 (1.5%)	1 (1.5%)	
<b>Outcome Measures</b>			
Decision Self Efficacy	79.83 (SD20.09)	84.24 (SD13.29)	0.36
HADS-Anxiety	6.41 (SD4.21)	7.03 (SD 0.54)	0.45
HADS-Depression	4.98 (SD3.84)	5.17 (SD3.80)	0.78



### 6.2.2. Protocol Compliance

The number of appointments attended by the participants varied. This meant the number of ‘Navigations’ an intervention participant received varied from a minimum of one to a maximum of four - see table 6.2. As detailed in the previous two chapters, the pragmatic decision was made to follow participants through all their required appointments to the end of treatment review. No significant differences were found between the number of appointments attended by the intervention group ( $M2.54, SD0.87$ ) and the control group ( $M2.58, SD0.76$ ;  $t(133)=-0.11, p=0.79$ ).

**Table 6.3.** Number of appointments attended at the clinic for all participants

<b>Number of appointments / Navigations</b>	<b>Control n = 67 (%)</b>	<b>Intervention n = 66 (%)</b>
1	9 (13.4)	11 (16.2)
2	12 (17.9)	15 (22.1)
3	44 (65.7)	36 (52.9)
4	2 (3.0)	6 (8.8)

#### *Full trial reasons for only one appointment:*

Control: ( $n=9$ ) Two participants died after their initial appointment. Five participants required no further treatment. Two withdrew after the first appointment; one was being treated in another hospital.

Intervention: ( $n=13$ ) Five participants withdrew after their first clinic appointment. One refused navigation for final two appointments but did not withdraw so was administered T6. Six required no further treatment. One died soon after their initial appointment.

#### *Full trial reasons for two clinic appointments*

Control: ( $n=12$ ) Eleven participants had to complete their treatment early due to side effects. One died after this appointment.

Intervention: ( $n=11$ ) Five participants finished treatment early due to side effects. Three participants died before their next appointment. One participant did not have a mid-treatment review appointment as decided by the clinic. Two participants had one appointment missed by the Navigation due to staffing resources.

*Full trial reasons for four Navigated appointments*

Control: ( $n=2$ ) Two participants had two initial appointments to decide treatment.

Intervention: ( $n=6$ ) Four participants had two initial appointments in addition to their mid-treatment and end of treatment review appointments. One participant had two mid treatment review appointments. One participant had two end of treatment review appointments in addition to the initial and mid treatment review appointments.

### 6.3. Results

#### 6.3.1. Primary Outcome Measure: Decision Self Efficacy (DSE)

Whole group scores of decision self-efficacy were high and remained high over the four time points of measurements for both groups, indicating a high level of confidence in the ability to make decisions. The intervention group mean score at baseline was higher than the control group, however as reported earlier this was not a significant difference, see Table 6.4.

**Table 6.4.** Mean scores of the Decision Self-Efficacy scale for all responders over time T1-T5 and per trial arm.

Time	Trial Arm	n	Mean	Std. Deviation
Baseline T1	Intervention	62	84.24	13.29
	Control	64	79.83	20.10
T3	Intervention	58	90.60	8.50
	Control	53	85.93	14.76
T4	Intervention	43	88.90	16.05
	Control	53	82.41	14.71
T5	Intervention	35	91.36	9.81
	Control	31	81.89	15.40

#### *DSE scores over time (T1, T3, T4, and T5) per trial arm*

The mixed ANOVA across all four time points was underpowered due to high levels of attrition and missing data.

There was a significant main effect of the trial arm  $F(1,43)=13.59, p=0.001$ , the rating of DSE differed between groups. Bonferroni corrected post hoc test showed that the intervention group ( $M90.26, CI95\% 86.44-94.07$ ) overall scored higher on the DSE ( $M_{diff}=11.03, CI95\% 4.99-17.60, p=0.001$ ) when compared to the control group ( $M79.23, CI95\% 74.56-83.90$ )

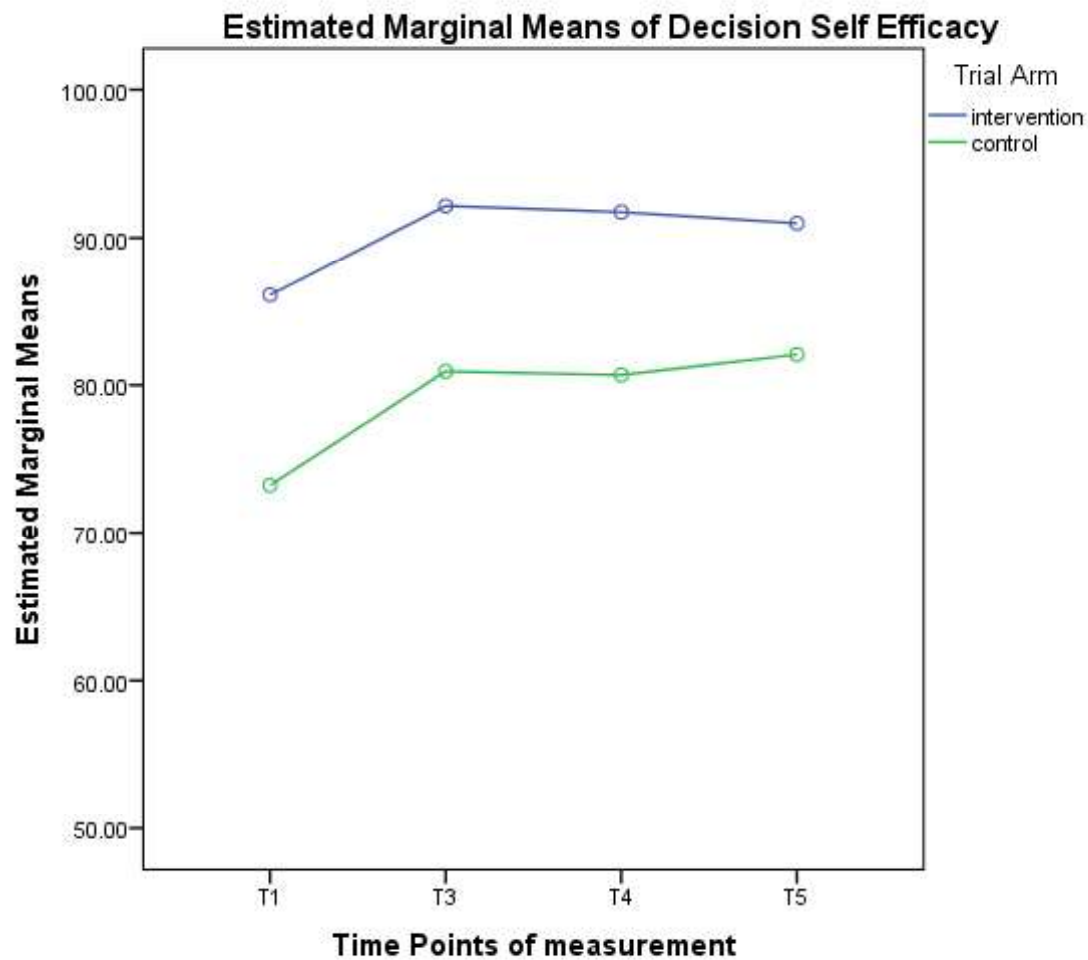
There was also a significant main effect of the time  $F(3,129)=5.19, p=0.007$ , the rating of DSE differed within groups over time. Bonferroni corrected post hoc test showed that rating of DSE from baseline to T3 did significantly differ ( $M_{diff}=6.88, CI95\% 0.51-13.25, p=0.028$ ). All other changes in DSE score across time were non-significant ( $p>0.05$ ).

However, a non-significant time x trial arm interaction was found  $F(1,129)=40.90, p=0.826$ , the rating of DSE over time did not differ between intervention and control groups, see table 6.5 and Figure 6.1. When applying the intention to treat principle to the primary outcome measure of decision self-efficacy this non-significant interaction between Time and Trial Arm is maintained (see Appendix 16).

**Table 6.5.** Mean scores of the Decision Self-Efficacy scale for all responders included in the Mixed ANOVA over time T1-T5 and per trial arm.

<b>Time</b>	<b>Trial Arm</b>	<b>n</b>	<b>Mean</b>	<b>Std. Deviation</b>
<b>Baseline T1</b>	Intervention	27	86.11	11.98
	Control	18	73.23	22.11
	Total	45	80.96	17.73
<b>T3</b>	Intervention	27	92.17	8.53
	Control	18	80.93	11.59
	Total	45	87.68	11.22
<b>T4</b>	Intervention	27	91.75	11.60
	Control	18	80.68	14.71
	Total	45	87.32	13.90
<b>T5</b>	Intervention	27	90.99	10.13
	Control	18	82.07	12.95
	Total	45	87.42	12.04

**Figure 6.2. Mean group DSE scores by time included in Mixed ANOVA**



#### *DSE scores over time (T1-T3) per trial arm*

There was a significant main effect of the trial arm  $F(1,103)=8.04, p=0.005$ , the rating of DSE differed between groups. Bonferroni corrected post hoc test showed that the intervention group ( $M=88.31, CI95\% 85.18-91.44$ ) overall scored higher on the DSE ( $M_{diff}=6.49, CI95\% 1.95-11.02, p=0.005$ ) when compared to the control group ( $M=81.82, CI95\% 78.54-85.10$ )

There was a significant main effect of the time  $F(1, 103)=13.53 p<0.001$ , the rating of DSE differed within groups over time. Bonferroni corrected post hoc test showed that the

intervention group overall scored higher on the DSE ( $M_{diff}=5.82$ ,  $CI95\%$  2.68-8.96,  $p>0.001$ ).

There was a non-significant time x trial arm interaction  $F(1,103)=96.81$ ,  $p=0.392$ , the rating of DSE over time did not differ in intervention and control groups, see table 6.7.

**Table 6.6.** Mean scores of the Decision Self-Efficacy scale for all responders included in the Mixed ANOVA over time T1-T3 and per trial arm.

Time	Trial Arm	Mean	Std. Deviation	N
<b>Baseline T1</b>	Intervention	86.07	10.53	55
	Control	78.22	21.70	50
	Total	82.34	17.17	105
<b>T3</b>	Intervention	90.54	8.63	55
	Control	85.41	13.29	50
	Total	88.10	11.34	105

*DSE scores over time (T1 and T2) intervention group only.*

A paired t-test compared the difference in DSE scores from baseline to post consultation planning, the first stage of the intervention, for the intervention participants only. A significant difference was found in the scores of the DSE measure from baseline ( $M83.91$ ,  $SD13.29$ ) to post consultation planning ( $M86.36$ ,  $SD13.00$ ,  $t(51)=-2.07$ ,  $p=0.044$ ).

Intervention participants rating of decision self-efficacy significantly increased after the consultation planning, when compared to their baseline score.

### 6.3.2. Secondary Outcome Measures

#### 6.3.2.1. Decision Conflict Scale (DCS)

This measure was taken four times; post initial consultation (T3) post mid treatment review (T4), post end of treatment review (T5) and follow up (T6).

Whole group scores of Decision Conflict Scale (DCS) were low (1 = low decision conflict, 5 = high) and remained low over the four time points of measurements for both groups, indicated by no score going above 2). The intervention group mean score was consistently lower than the control group, see Table 6.7 in the DCS scores between groups section.

#### *DCS scores over time (T3, T4, T5, and T6) per trial arm*

The mixed ANOVA across all four time points was underpowered due to high levels of attrition and missing data.

There was a significant main effect of the trial arm  $F(1,34)=6.19, p=0.018$ , the rating of DSE differed between groups. Bonferroni corrected post hoc test showed that the intervention group ( $M1.58, CI95\% 1.42-1.73$ ) overall scored lower on the DCS ( $M_{diff} = -0.29, CI95\% -0.53- -0.05, p=0.018$ ) than the control group ( $M1.87, CI95\% 1.69-2.05$ ).

There was a non-significant main effect of the time  $F(3,102)=0.19, p=0.996$ , the rating of DSE did not differ within groups over time.

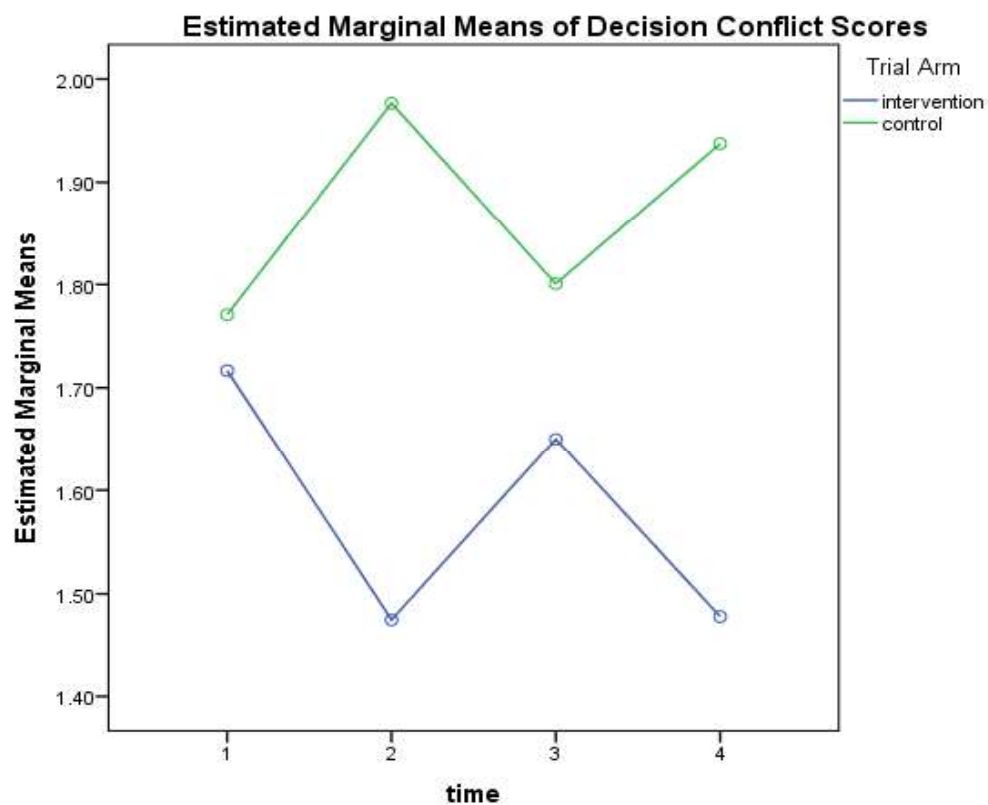
There was also a non-significant time x trial arm interaction  $F(3,102)=1.09, p=0.355$ , the rating of DSE over time when intervention group and control group means scores were compared, see table 6.7. Figure 6.3 shows the pattern of changes of group mean score over

time per group. The comparison of DCS scores at the individual time points will be analysed further in the next section.

**Table 6.7.** Mean scores of the Decision Conflict scale for all responders included in the Mixed ANOVA over time T3-T6 and per trial arm.

Time	Trial Arm	N	Mean	Std. Deviation
<b>T3</b>	Intervention	20	1.72	0.85
	Control	16	1.77	0.57
	Total	36	1.74	0.73
<b>T4</b>	Intervention	20	1.48	0.68
	Control	16	1.98	0.57
	Total	36	1.70	0.67
<b>T5</b>	Intervention	20	1.65	0.86
	Control	16	1.80	0.47
	Total	36	1.71	0.71
<b>T6 Follow up</b>	Intervention	20	1.48	0.45
	Control	16	1.94	0.54
	Total	36	1.68	0.54

**Figure 6.3.** Mean group DCS scores by time included in Mixed ANOVA T3-T6





### *DCS scores between groups T3-T6*

Independent t-tests compared group mean scores of DCS between groups at individual time points, see table 6.8.

Post consultation (T3) a non-significant difference was found between group mean scores of DCS ( $t(106)=-1.40, p=0.164$ ). Control participants score of DCS ( $M1.75, SD0.74$ ) were not significantly different to intervention participants rating ( $M1.96, SD0.78$ ).

Following the mid treatment consultation (T4) a significant difference was found between group mean scores of DCS ( $t(84)=-2.76, p=0.007$ ), the intervention group ( $M1.60, SD0.73$ ) reported lower scores of decision conflict when compared with control participants ( $M1.99, SD0.56$ ).

Post end of treatment (T5) review a non-significant difference was found between group mean scores of DCS ( $t(60)=-1.25, p=0.216$ ), although the intervention group ( $M1.70, SD0.78$ ) scored lower on the DCS when compared with control participants ( $M1.91, SD0.54$ ).

At follow up (T6) a non-significant difference was found between group mean scores of DCS ( $t(67)=-1.76, p=0.082$ ). Again the intervention group ( $M1.48, SD0.50$ ) scored lower on the DCS when compared with control participants ( $M1.70, SD0.54$ ).

**Table 6.8.** Mean scores of the Decision Conflict scale for all responders over time and per trial arm.

Time	Trial Arm	n	Mean	Std. Deviation	p value	95% Confidence Interval	
						Lower	Upper
T3	Intervention	55	1.75	0.74	0.164	-0.49	0.08
	Control	53	1.96	0.78			
T4	Intervention	43	1.60	0.73	0.007	-0.67	-0.11
	Control	25	1.99	0.56			
T5	Intervention	32	1.70	0.78	0.216	-0.55	0.13
	Control	38	1.91	0.54			
T6	Intervention	35	1.48	0.50	0.082	-0.47	0.02
	Control	34	1.70	0.54			

### 6.3.2.2. Decision Regret

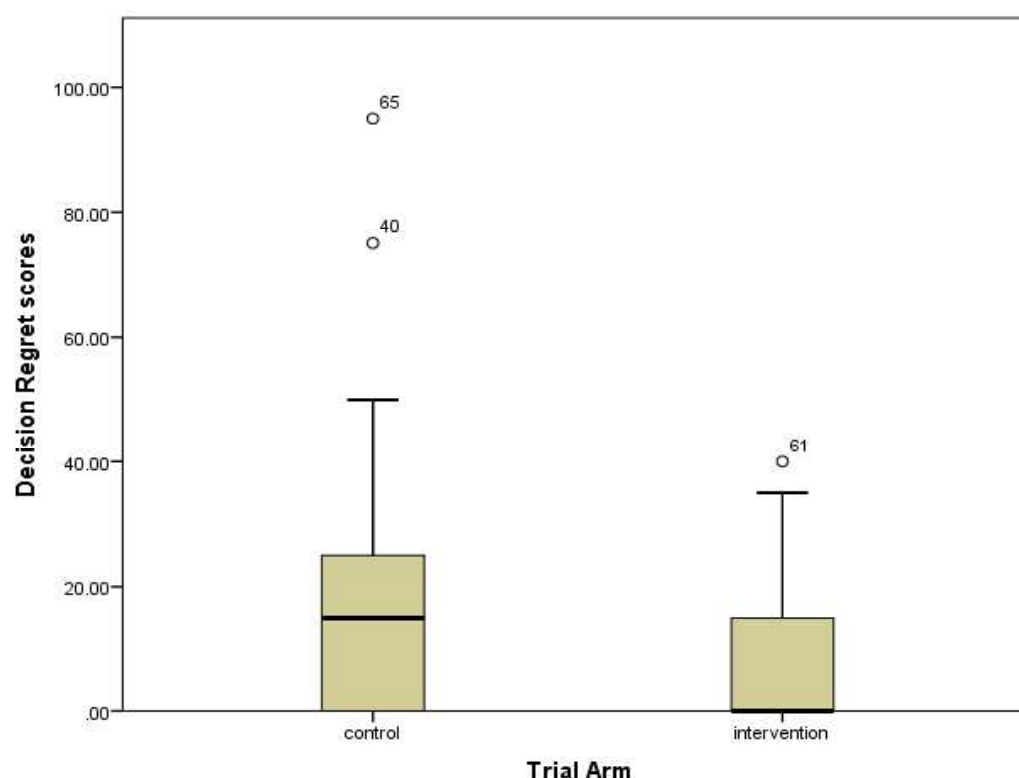
The decision regret scale (DRS) was administered once at follow up (T6). A high number (1-5) indicated more regret.

An independent samples *t*-test was conducted to compare the Decision Regret score for the intervention and control group at T6. A significant difference in scores was found between intervention ( $M9.32, SD12.26$ ) and control ( $M19.03, SD22.86$ ;  $t(44.07) = -2.12, p=0.039$ ) see table 6.9. The magnitude of the differences in the means ( $M_{diff} = -9.71, CI95\%: -18.92$  to  $-0.49$ ) was moderate (eta squared = 0.064) see figure 6.11. These results indicate that those in the intervention arm experienced less regret when compared with those in the control arm.

**Table 6.9.** Mean scores for the Decision Regret Scale at follow up (T6).

	Mean score (SD)	Mean difference	p value
Control (n=31)	19.03 (22.89)	-9.71 (1.02-18.39)	0.039
Intervention (n=37)	9.32 (12.26)		

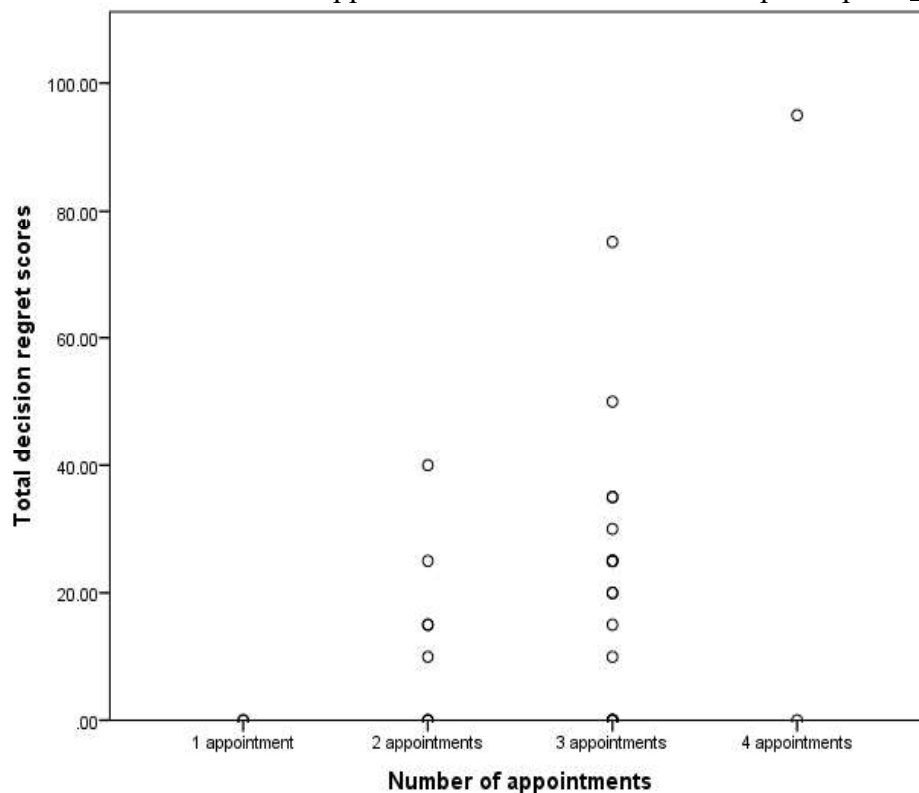
**Figure 6.4.** Mean changes in Decision Regret Scores between groups at follow up (T6)



#### *Relationship between amount of oncology appointments and DR score*

As previously reported, the number of appointments attended, and therefore the amount of intervention exposed to, varied amongst participants from a minimum of one to a maximum of four. To explore if there was a relationship between the number of appointments attended and DRS score a scatter plot was generated which indicated some level of positive relationship, however a non-significant correlation was reported ( $r(66)=0.22, p=0.08$ ). This non-significance was maintained when exploring the relationship between number of appointments attended within the intervention participant ( $r(35)=-0.05, p=0.74$ ). However a positive relationship was found for control participants  $r(29)=0.38, p=0.038$ , indicating for control participants that as the number of appointments increased so too did their DRS score, see Figure 6.5.

**Figure 6.5** A scattergram to show the relationship between the spread of DRS scores and number of appointments attended for control participants.



### 6.3.2.3. Preparation for decision making scale.

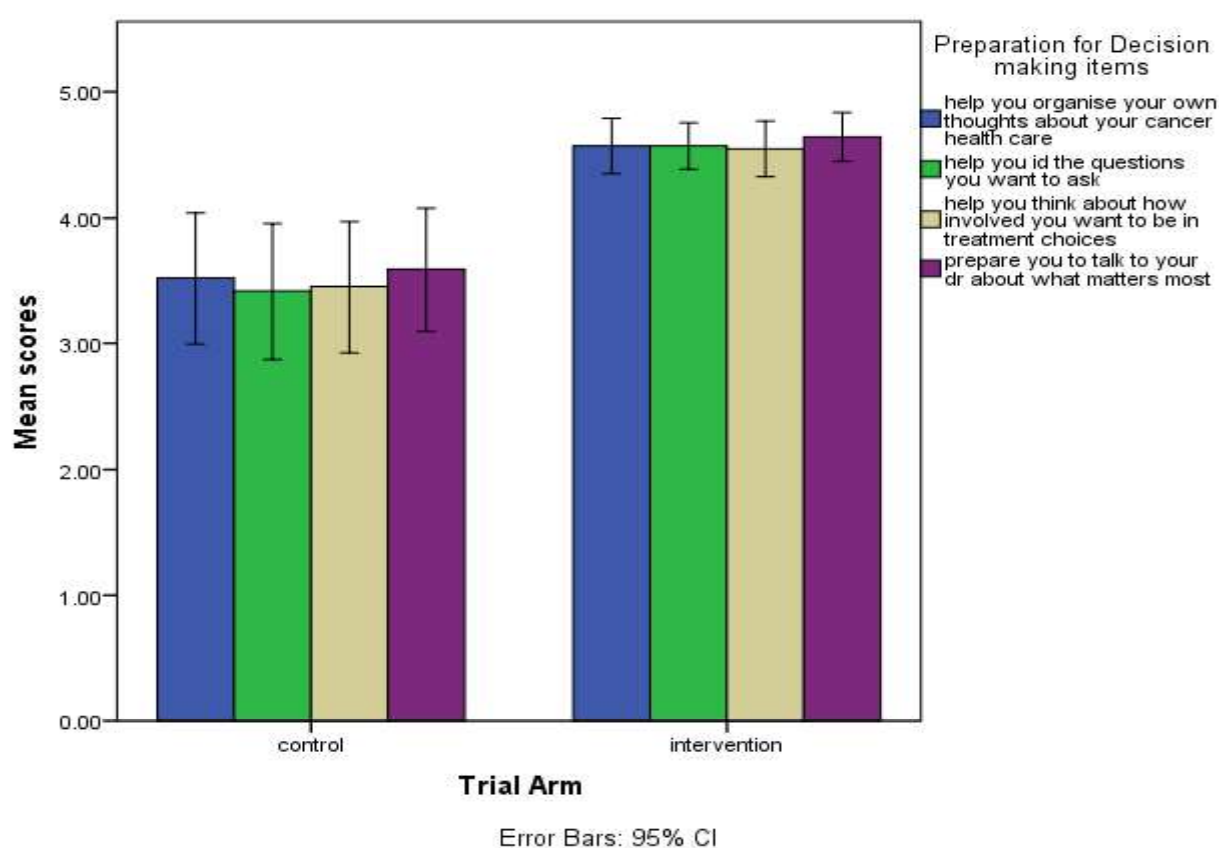
This measure was taken after each consultation (T3, T4 and T5) and consisted of four items to assess how prepared a participant was for their consultation. Mann Whitney U tests were used to explore the differences of scores between groups as all item scores at each time point violated the assumption of homogeneity of variance (Levene's test).

At T3 for all four items the intervention participants scored significantly higher ( $p > 0.001$ ) than control participants, see table 6.10 and figure 6.6.

**Table 6.10** Mean scores for the Preparation for Decision Making Scale at post initial consult (T3).

Items scored	Control	Navigation	<i>U</i>	<i>p</i> value
Not at all 1-2-3-4-5 A great deal	n=52	n= 62		
	<i>M (SD)</i>	<i>M (SD)</i>		
Organise your own thoughts about the decision	3.98 (0.91)	4.60 (0.59)	752.00	0.00
Identify the questions you want to ask your doctor	3.84 (1.03)	4.67 (0.57)	952.50	0.00
Think about how involved want to be in decision	3.92 (0.94)	4.50 (0.75)	920.50	0.00
Talk to your doctor about what matters most	4.10 (0.78)	4.69 (0.53)	878.00	0.00

**Figure 6.6.** Mean scores for preparation for decision making items per trial arm at T3

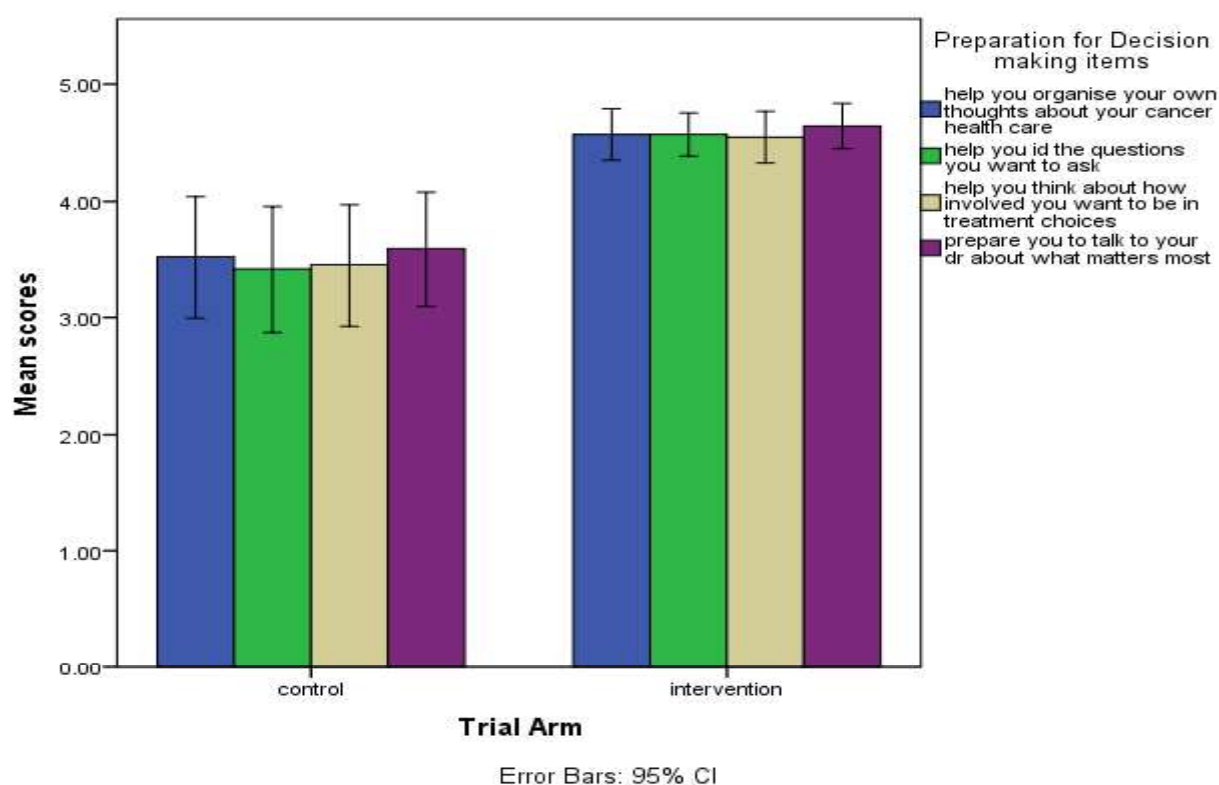


At T5 for all four items the intervention participants scored significantly ( $p>0.001$ ) higher than control participants, see table 6.11 and figure 6.7.

**Table 6.11.** Mean scores for the Preparation for Decision Making Scale at mid treatment (T4)

Items scored:	Control	Navigation	<i>U</i>	<i>p</i> value
Not at all 1-2-3-4-5 A great deal	n=29	n= 42		
	<i>M (SD)</i>	<i>M (SD)</i>		
Organise your own thoughts about the decision	3.52 (1.39)	4.57 (0.70)	318.50	0.00
Identify the questions you want to ask your doctor	3.41 (1.43)	4.57 (0.60)	305.00	0.00
Think about how involved want to be in decision	3.45 (1.38)	4.55 (0.71)	309.00	0.00
Talk to your doctor about what matters most	3.59 (1.30)	4.64 (0.62)	878.00	0.00

**Figure 6.7.** Mean scores for preparation for decision making items per trial arm at T4

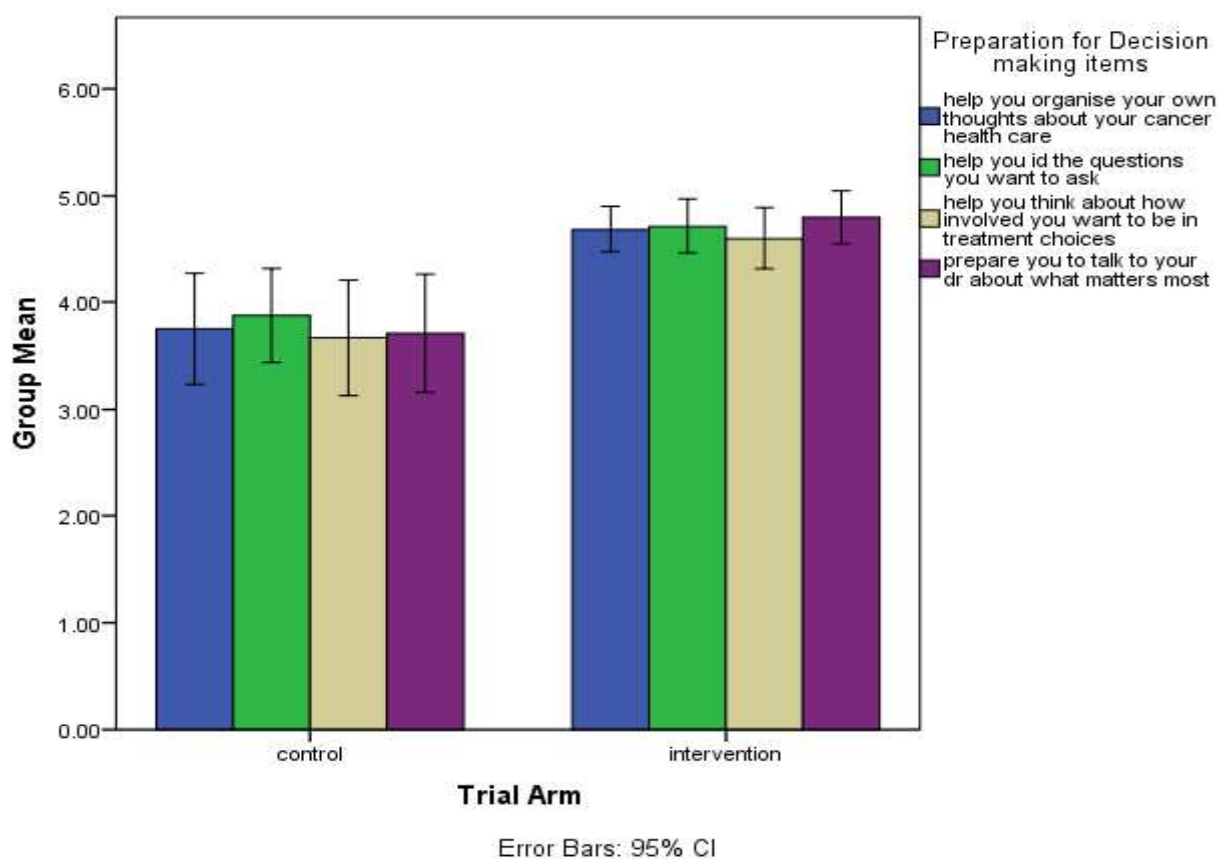


At T6 for all four items the intervention participants scored significantly ( $p>0.001$ ) higher than control participants, see table 6.12 and figure 6.8.

**Table 6.12.** Mean scores for the Preparation for Decision Making Scale at end of treatment review appointment (T5).

Items scored:	Control	Navigation	<i>U</i>	<i>p</i> value
Not at all 1-2-3-4-5 A great deal	n=25 <i>M (SD)</i>	n= 35 <i>M (SD)</i>		
Organise your own thoughts about the decision	3.84 (1.03)	4.71 (0.75)	169.00	0.00
Identify the questions you want to ask your doctor	3.67 (1.27)	4.60 (0.84)	206.50	0.00
Think about how involved want to be in decision	3.76 (0.93)	4.69 (0.63)	200.00	0.00
Talk to your doctor about what matters most	3.68 (1.28)	4.80 (0.72)	168.00	0.00

**Figure 6.8.** Mean scores for preparation for decision making items per trial arm at T5



### *Summary of Preparing for decision making scores*

Intervention participants reported overall higher scores on the four items from the Preparation For Decision Making scale when compared to control participants at each time point (T3, T4 and T5) ( $p>0.001$ ).

### *Satisfaction with Intervention*

Intervention participants were asked to rate their satisfaction of the intervention on a scale of one-ten (1 not at all satisfied – 10 extremely satisfied) after each consultation T3, T4 and T5. The majority of participants were highly satisfied with their experience, see Table 6.13.

**Table 6.13** Intervention participant satisfaction scores over three timepoints(T3, T4,T5).

Timepoint	Mean	Standard Deviation	Score Range	
			Min	Max
T3 (n=62)	9.08	1.27	2	10
T4 (n=41)	9.37	0.83	7	10
T5 (n=35)	9.34	1.39	3	10



#### 6.3.2.4. Hospital Anxiety and Depression Scale

Participants completed the HADS a 14 item measure at baseline (T1) and follow up (T6); seven items measured anxiety and seven measured depression. Group mean HADS scores for anxiety and depression for both trial arms decreased from baseline to follow up see table 6.14 and 6.15 and Figure 6.9, indicating an overall reduction in all participant's reporting of anxiety and depression over the study period.

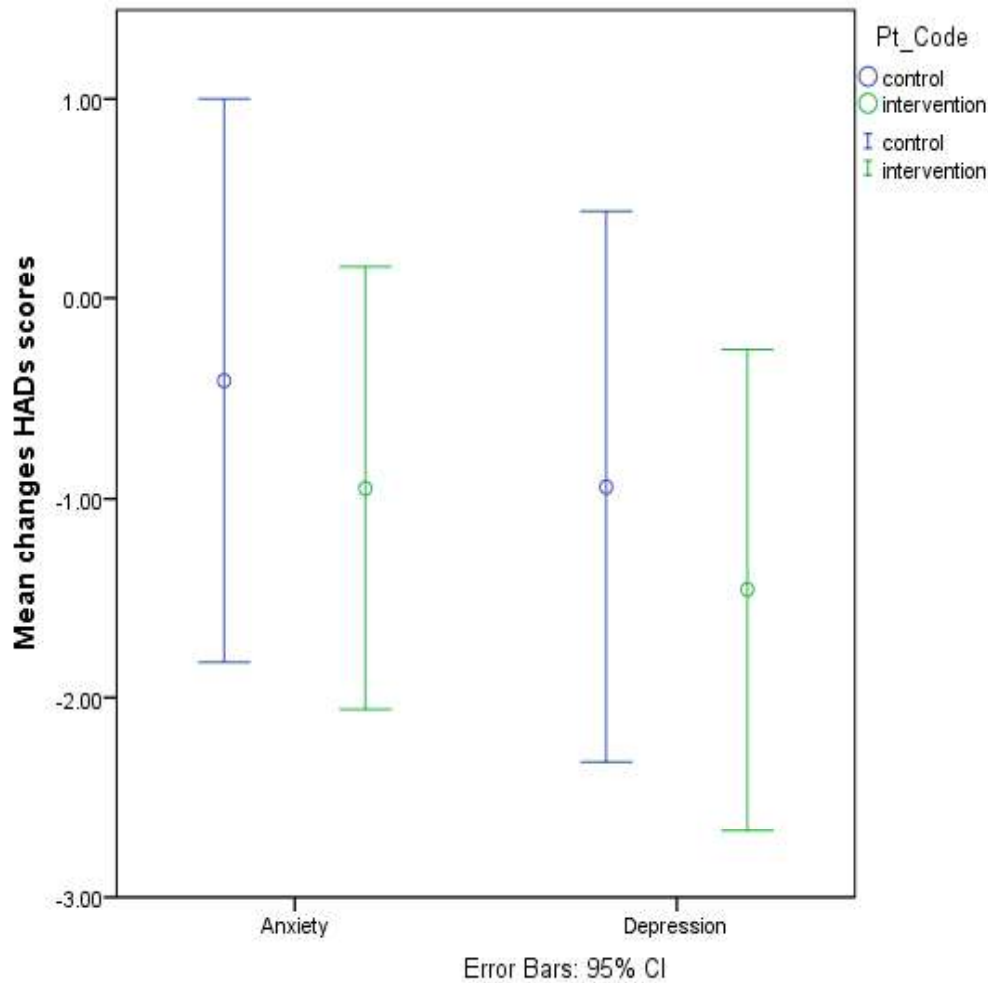
**Table 6.14.** Group mean anxiety scores by trial arm over time (T1-T6).

	Mean baseline score (SD) (n)	Mean Follow up score (SD) (n)
<b>Intervention</b>	7.03 (4.29) (n=64)	5.67 (4.13) (n=39)
<b>Control</b>	6.41 (4.21) (n=64)	5.94 (4.49) (n=34)

**Table 6.15.** Group mean depression scores by trial arm over time (T1-T6).

	Mean baseline score (SD)(n)	Mean Follow up score (SD)(n)
<b>Navigation</b>	5.17 (3.80) (n=63)	3.49 (3.30) (n=39)
<b>Control</b>	4.98 (3.84) (n=65)	3.91 (3.79) (n=35)

**Figure 6.9.** Mean change in HADS scores from Baseline (T1) to follow up (T6) per trial arm.



#### *HADS-Anxiety scores (T1 and T6) per trial arm*

There was a non-significant main effect of the trial arm  $F(1,71)=0.005$ ,  $p=0.943$ , the rating of HADS-A did not significantly differ between overall groups scores, disregarding time point.

There was a non-significant main effect of the time  $F(1,71)=2.42$ ,  $p=0.124$ , the rating of HADS-A did not differ over time disregarding Trial Arm.

A non-significant Time x Trial Arm interaction was found  $F(1,71)=0.38$ ,  $p=0.541$ , the rating of HADS-A over time did not differ between intervention and control groups, see table 6.15.

**Table 6.16.** Mean scores for the HADS-A at baseline (T1) and follow up (T6) included in the mixed ANOVA.

<b>Time</b>	<b>Trial Arm</b>	<b>n</b>	<b>Mean</b>	<b>Std. Deviation</b>
<b>T1</b>	Intervention	39	6.62	3.92
	Control	34	6.41	4.72
<b>T6</b>	Intervention	39	5.67	4.13
	Control	34	6.00	4.46

*Clinical thresholds of anxiety*

Descriptive statistics were calculated using a clinical cut-off point of eight, to indicate a borderline state of anxiety and ten to indicate a clinical presence of anxiety (Zigmond & Snaith, 1983; Patel, et al., 2010).

At baseline, 128 participants completed the anxiety subscale measure. Of these, 24 participants (16 intervention, 8 control) (18.75%) reached the threshold of clinical anxiety ( $\geq 10$ ), while 23 (17.97%) participants (10 intervention, 13 control) scored borderline ( $\geq 8$ - $\leq 10$ ).

At follow up 15 participants (8 intervention, 7 control) (20.56%) reached the threshold for anxiety ( $\geq 10$ ) out of 73 participants who completed the scale, 9 participants scored borderline ( $\geq 8$ - $\leq 10$ ) (4 intervention, 5 control) (12.16%).

Using a threshold of  $\geq 8$  on the whole data set, 36.72% (40.6% intervention, 32.81% control) of this population were highly anxious at baseline; at follow up 32.43% (30.77% intervention, 34.29% control) at follow up. Table 6.17 shows the mean scores for all participants who completed the anxiety subscale.

**Table 6.17.** Frequency of clinical anxiety threshold ( $\geq 10$ ) scores by trial arm over time.

	Baseline			Follow Up		
	n (%)	Range		n (%)	Range	
		Min	Max		Min	Max
<b>Intervention</b>	16 (25%)	10	20	8 (20.51%)	10	19
<b>Control</b>	8 (12.5%)	10	20	7 (20.59%)	12	17

#### *HADS-Depression scores (T1 and T6) per trial arm*

There was a non-significant main effect of the trial arm  $F(1,71)=0.01$ ,  $p=0.920$ , the rating of HADS-D did not differ between groups, disregarding the time point.

There was a significant main effect of the time  $F(1,71)=7.15$ ,  $p=0.009$ , the rating of HADS-D did differ over time. From baseline to follow up overall HADS-D scores, disregarding Trial Arm, decreased ( $M_{diff}=-1.20$ ,  $CI_{95\%}$  0.31-2.10,  $p=0.009$ ).

A non-significant time x trial arm interaction was found  $F(1,71)=0.34$ ,  $p=0.564$ , the rating of HADS-D over time did not differ between intervention and control groups, see table 6.18.

**Table 6.18.** Mean scores for the HADS-D at baseline (T1) and follow up (T6) included in the mixed ANOVA.

<b>Time</b>	<b>Trial Arm</b>	<b>n</b>	<b>Mean</b>	<b>Std. Deviation</b>
<b>T1</b>	Intervention	39	4.95	3.65
	Control	34	4.76	4.26
<b>T6</b>	Intervention	39	3.49	3.30
	Control	34	3.82	3.81

### *Clinical thresholds of depression*

Descriptive statistics were calculated using a clinical cut-off point of eight to indicate a borderline state of depression and ten used to indicate a clinical presence of depression (Zigmond & Snaith, 1983; Patel, et al., 2010).

From the 63 participants who completed the depression subscale at baseline 14 participants (seven control, seven intervention) (22.22%) scored  $\geq 10$  indicating a potential diagnosis of depression, 12 (19.05%) scored borderline ( $\geq 8 - \leq 10$ ) (7 intervention, 5 control).

At follow up, 74 participants completed the measure, of this sample 7 participants (9.46%) reached the cut-off point indicating a borderline state of depression ( $\geq 8 - \leq 10$ ) (5 intervention, 2 control) while three participants (one control, two intervention) (4.05%) scored  $\geq 10$ .

Using a threshold of  $\geq 8$  on the whole data set, 20.31% (22.22% intervention, 18.46% control) of this population were highly depressed at baseline; at follow up this reduced to 13.51% (17.95% intervention, 8.57% control) scored. Table 6.19 shows the mean scores for all participants who completed the depression subscale.

**Table 6.19.** Frequency of clinical depression ( $\geq 10$ ) threshold scores by trial arm over time.

	Baseline (T1)			Follow Up (T3)		
	n (%)	Range		n(%)	Range	
		Min	Max		Min	Max
<b>Intervention</b>	7 (11.11%)	10	19	2 (5.13%)	11	12
<b>Control</b>	7 (10.77%)	10	18	1 (2.86%)	20	20

#### **6.4. Summary of the RCT results.**

The primary outcome measure of this study was the Decision Self-Efficacy scale. No significant difference was found in scores of DSE between Trial arms and over time. In the secondary outcome DCS again no significant difference in the scores was found between trial arms over time. When the DCS scores were analysed at each time point there were no significant differences between groups for T3 and T5, however at T4 the intervention group reported significantly lower decision conflict when compared to the control group. At follow up a significant difference was found between the score of Decision regret between groups. Intervention groups reported lower scores of regret. . In addition a positive correlation between number of appointments attended and increasing regret score was found for control participants only. At each time point after the consultation (T3, T4 and T5) intervention participants scored significantly higher on the Preparation for Decision Making scale, indicating a high sense of feeling prepared. Overall intervention participants rated their satisfaction as high across the time. No significant differences were found between groups over time on both the HADS subscales (anxiety and depression).

These results will be discussed further in the context of current knowledge and the qualitative evaluation of the intervention in chapter nine, the discussion. The next Chapter (7) will describe the qualitative evaluation methodology followed by the qualitative findings in Chapters 7 and 8.

## **Chapter 7: Qualitative evaluation of patient and clinicians' perspective**

### **7.1. Introduction**

Following the previous chapters, which outlined the randomised controlled trial methodology and results of the intervention with colorectal cancer patients, this chapter presents the methodology used to explore patient and clinician experiences of Navigation and usual care. This was achieved through undertaking a qualitative study as part of this thesis. The chapter begins by documenting the process of designing the qualitative component of this research and subsequently outlines and provides rationale for the methods chosen. There then follows a description of the qualitative research methods utilised with the sample population of: colorectal cancer participants, high grade glioma participants and health care professionals.

### **7.2. Philosophical underpinning of qualitative inquiry**

The philosophical foundations of naturalistic inquiry, undertaking study of a phenomena in its natural setting, argue that '*individuals create their own subjective realities, and thus the knower and the knowledge are interrelated and interdependent*' (p 46, DePoy & Gitlin, , 2011). Within this philosophy, an individuals' ideas and interpretations are the lenses through which they know the universe (DePoy & Gitlin, 2011). Qualitative research therefore is characterised by; exploring phenomena from the respondent's perspective with the use of methods sensitive to the context; the capture of detailed and rich data, utilising a mainly inductive process; and developing explanations at the level of meaning (Spencer et al., 2003). As such, qualitative research aims to answers questions such as what is X, how does it vary in circumstances and why? (Pope, Ziebland & Mays, 2000).

There is a recognised competition between qualitative and quantitative philosophies, with quantitative methodologies, in particular the randomised controlled trial, residing dominant within health-related research. Although quantitative research may be able to demonstrate statistically significant and so generalisable results from a large population, it has limited use in adequately exploring why or how a phenomenon occurs (Silverman, 2009), for example in building understanding of the cancer experience. To understand meaning that people attach to their experiences of the social world and how they make sense of that world, qualitative research can provide the in-depth and exploratory tools needed to produce a clear depiction (Symon & Cassel, 1998). As Barbour (2008) explains: ‘Qualitative research can make visible and unpick the mechanisms which link particular variables by looking at explanations or accounts, provided by those involved’ (p11).

As this world view is constructed and interpreted by people themselves, naturalistic inquiry proposes that the social world cannot be reduced to purely that which is observable and manipulated (Holloway, 2005). Research conducted in this paradigm uses systematic approaches to collect empirical data, organise and interpret such data usually obtained through talking with people or through observation in the natural setting. Qualitative methodology facilitates researchers to reveal a novel and insightful way of understanding the perspective of the respondent, and has application in the context of oncology as increasingly multi-disciplinary research teams attempt to tackle the psycho-social aspects of cancer (McPherson & Leydon, 2002).



### **7.3. Qualitative research in healthcare and complex intervention evaluation**

A qualitative approach to inquiry has become accepted and established within health services research (Mays & Pope, 2000) and increasingly within health care evaluation (Lewis, 2007). Qualitative evaluation is operationalized as research which aims to appraise how a service or innovation, in this thesis Navigation, is implemented, and whether it achieves its objectives, with a view to understanding its effectiveness (Lewis, 2007). The field of using qualitative research for evaluation purposes is relatively early in its development. Such evaluation within a naturalistic setting requires analysis and description of people's meanings and interpretations of the social world examined with their natural 'real' world context (Brewer, 2003). Qualitative approaches in evaluation aim to holistically understand the phenomena from the insider perspectives of participants (patients) and other stakeholders (clinicians) (Abma & Widdershoven, 2011).

Qualitative research is now used in evaluation for a range of purposes. Ritchie and Spencer (1994) propose evaluation research seeks to address four categories of objectives, namely: contextual, identifying the form and nature of what exists; diagnostic, examining reasons for, or causes of, what exists; evaluative, appraising the effectiveness of what exists: and strategic, identifying new theories, plans or actions. More specifically, Spencer et al., (2003) highlight qualitative evaluative research can: identify the factors that contribute to successful or unsuccessful delivery; identify outcomes (intended or unintended) and how they occur; examine the nature of requirements of different groups within the target population; and explore organisational aspects of delivery. Within the evaluation of a complex intervention Lewin, Glenton & Oxman (2009) recommend a qualitative element has many beneficial functions according to when it is implemented; before, during or after a randomised controlled trial. In this thesis the qualitative element of the study was conducted at the end of

a participant's engagement with the intervention therefore it corresponds with the functions after a trial. After a trial, Lewin, et al., (2009) propose the qualitative approach contributes to the overall evaluation through: exploring reasons for the findings of the trial, explaining variations in effectiveness within the sample, examining the appropriateness of the underlying theory, and generating further questions or hypotheses (p.2). In a review of the literature of qualitative studies that evaluated RCTs for complex intervention Lewin et al. (2009) found very few integrated the results of both paradigms. This thesis follows Gutterman, Fetters & Creswell's (2015) convergent model to integrate the findings at the contextual level, within the discussion of this thesis.

For this evaluation, the study is primarily interested in understanding the acceptability, impact and feasibility of Navigation, grounded in the experiences and views of patients and clinicians. The qualitative methods utilised will thereby provide a more detailed and nuanced information than the data generated through an RCT alone (Sandelowski, 1996).

#### **7.4. Study design**

A prospective qualitative design was used to evaluate the Navigation intervention from the perspective of patients and their clinicians. Qualitative in-depth interviews were used to collect data. The sample was drawn from patients with CRC involved in the intervention arm (Navigated patients) and control arm (usual care). Participants were also recruited who had HGG and received the intervention. Consulting clinicians involved in the care of HGG and CRC patients were also recruited. Data was collected in a single face-to-face or telephone semi-structured interview that explored the areas of decision making and communication in the consultations (all patients and clinicians) and the impact of the intervention (Navigated

patients and clinicians). Two interview guides (patient and clinician) were used to direct interview questioning. Framework analysis was undertaken.

## **7.5. Study settings and sample**

The settings in which this study occurred have been detailed in Chapter 4 section 4.4. In summary, the qualitative evaluation was conducted in a regional, tertiary cancer centre in Scotland.

Sampling in qualitative research is driven by a different set of concerns when compared to quantitative research. As stated by Mays and Pope (1996) “the purpose [of sampling in qualitative research] is to identify specific groups of people who either possess characteristics or live in circumstances relevant to the social phenomenon being studied” (p.12). The sampling strategy was purposeful in that participants were recruited based on having experiences relevant to the aims of the study. Details of the recruitment of patient and clinicians for the qualitative component of the evaluation are now presented.

### **7.5.1. Sample and recruitment procedures: Colorectal cancer (CRC) participants**

In order to obtain a more detailed insight into the experiences of decision making and communication within the consultation in usual care and with the intervention, a subsample of the control and intervention participants from the RCT were invited to interview.

Invitation’s for interviews occurred over a four month period towards the end of the trial. The study aimed to recruit ten control and ten intervention participants. The sampling frame for this evaluation was formed by those who gave their consent to be contacted for interview at baseline. The inclusion criteria included; trial participants who had consented for interview at baseline and attended three consecutive clinic appointments; an initial treatment appointment,

a mid-treatment review appointment and an end of treatment appointment. Exclusion criteria included; participants who did not consent to be contacted for interview at baseline and those who had attended two or fewer clinic appointments as the aim of the qualitative evaluation was to gather experiences of repeated consultations and compare the longitudinal experience of Navigation with usual care.

Qualitative interviews were conducted within one month of a participant completing the end of treatment review appointment. Stratified purposeful sampling (Sandelowski, 2000) was utilised to select participants within intervention and control groups, purposively chosen to include those with palliative disease and curative disease. These groups were chosen due to the different contexts of treatment decisions (curative and palliative) and the potential comparisons between CRC and HGG. This type of sampling is informationally representative (Sandelowski, 2000).

As this trial was longitudinal in nature the main researcher was very familiar with the participants. To reduce any potential bias in the selection of participants e.g. those favourable with the intervention, and in keeping with the evaluative nature of this research, an independent and remote researcher selected participants for interview. All eligible participants at the current time point were assigned number codes and grouped according to trial arm and disease stage. The independent researcher randomly picked twelve from each group, to account for decliners. This was an iterative process that ran concurrent with the main study trial.

Selected participants were invited to interview via a telephone call. The telephone call included a verbal explanation of the interview process, together with the opportunity to

discuss and ask questions. Scheduling the interview was arranged according to the patient's convenience and availability. As the aim of this study was to develop a qualitative understanding of the experience of the intervention, and generate ideas to further understand the RCT findings, the sample size was deemed adequate for this evaluation and to achieve data saturation.

#### **7.5.2. Sample and recruitment procedures: High Grade Glioma (HGG) participants.**

As previously highlighted, the number of people diagnosed with a HGG at the study site was variable. Recruitment occurred over a 14 month period, and based on an assumed 30% recruitment rate, the aim was to recruit 36 participants during that time. The inclusion criteria were: all patients newly diagnosed with a HGG and all patients aged over 18. The exclusion criteria were patients who had:

- severe physical illness and considered too ill or distressed on assessment by the clinic team to be involved in the study;
- identifiable severe psychiatric morbidity or limited ability to understand and to engage in the intervention;
- diminished cognitive capacity and unable to make an informed autonomous decision about taking part in the study;
- inability to speak and comprehend English.

Recruitment for the HGG group was informed by a flexible, pragmatic sampling approach, using purposeful sampling (Marshall, 1996). It was anticipated that recruitment from this patient group would be challenging and time intensive as HGG is a rare cancer with patients, at the point of recruitment, being generally unaware of their diagnosis. An initial sample of seven patients was consecutively recruited. The demographics of these participants were then reviewed and subsequent recruitment was then directed to ensure diversity by age and gender, thus exploring any potential differing experiences related to these areas. In reality this method

became difficult and subsequently a convenience sample of participants were invited for pragmatic reasons such as limited time left for the study to run. If the participant's next of kin/relatives/carers of patient wished to be present or take part in the interview, verbal consent was obtained from both parties.

Potential HGG participants were identified through the weekly multi-disciplinary team meeting and confirmed by the neuro-surgical team (including the consultants and specialist nurse) according to the inclusion/exclusion criteria. Patients were invited to the study at one of three time points; at pre-assessment clinic before their surgery, on the neuro-surgical hospital ward before their surgery or a few days after their surgery in the neuro-surgical hospital ward. Those invited at the pre-assessment clinic were re-assessed for eligibility after their surgery and the study team met with them again on the ward post-surgery. Initial contact was made by a member of the health team who then introduced the researcher to the patient. At first contact patients were provided with a verbal explanation of the study alongside an invitation sheet, information sheet and example consent form (see Appendix 17, 18 & 19). Opportunity for questions was made available. A second time for follow up contact was arranged. A minimum of 24 hours was given for patients to decide if they would like to participate. When a patient agreed to participate they completed the consent form. No repeat approaches were made. Those who did not wish to take part in the study were not contacted again. All participants who consented received the intervention.

At the first Navigated clinic appointment, patients received the results of their surgery and were informed of their formal diagnosis, a high grade glioma, an incurable and severely life-limiting brain tumour. The pre-diagnosis period is a critical time that can either preclude or facilitate smooth and rapid transition from being a person with symptoms to becoming a patient with a confirmed cancer diagnosis (Leydon, Bynoe-Sutherland & Coleman, 2003). As

such, it was important the intervention be put in place before a patient had received their formal diagnosis, in order to support participants for their first consultation appointment. Therefore patients were invited into the study whilst on the ward recovering from brain surgery for their HGG. At this point of invitation the majority of patients at this point were not aware of the gravity of their condition. Furthermore, it was quickly discovered the majority of participants were not aware they would need to attend a clinic appointment to hear the results of their surgery. Through negotiation with the neuro-surgeons throughout the study period, it was agreed patients would be informed earlier post-surgery that attendance at clinic would be the next stage in their management and this was then highlighted to ward staff. Participants were often very pleased to understand more about what would happen next. All interviews were arranged and conducted at the participant's convenience.

As noted previously in this work, this thesis reports on part of a larger evaluation study. In this, Navigation participants engaged in serial evaluation interviews throughout their first line treatment (baseline, mid treatment and end of treatment). However, in order to enable comparison with the experiences of other groups involved in this qualitative evaluation, this thesis will only report on the final interview conducted with HGG participants within one month of their end of treatment review.

### **7.5.3. Sample and recruitment procedures: Clinicians**

To gain a multi-perspective approach about the intervention impact, consulting clinicians were also interviewed about the experience of using Navigation. The aim of bringing data from another appropriate source was to add richness to the context of the data, provide a more detailed understanding from a different perspective, and use this to help inform relevant and workable recommendations for improving health care services (Kendall et al., 2007).

Following the end of patient recruitment to the trials, all consulting clinicians who had first-hand experience of Navigated patients were invited to a single face-to-face interview in order to explore their views and attitudes about the Navigation intervention.

The potential sample was self-selected from four colorectal consultants and three neuro-oncology consultants and one senior registrar. Inclusion criteria encompassed; consulting with an intervention participant over the three consecutive appointments (initial, mid & end time points) with three or more participants. Exclusion criteria included; consulting intervention less than three participants for less than three appointments or consulting for each appointment but fewer than three times. Invitations to participate in the interviews were made via email. A convenient time and place for interview was agreed with those wishing to participate. No follow-up emails were sent to non-responders or those who declined. Clinicians were asked to sign a consent form (Appendix 20) prior to commencement of the interview.

## **7.6. Research Methods: the qualitative research interview**

Interviews form an essential part of qualitative data collection and provide a rich and important contribution to understanding participants' experience (Fetterman, 2010). A semi structured approach was used to conduct the interviews as the evaluation aimed to understand participants' perspectives on decision making and communication within the consultation and the impact of the intervention on these experiences. Two interview guides (Appendix 21 & 22) were developed that outlined key areas for exploration with each group of participants (patients and clinicians). The interview guides were important in building the language used in interviews, thereby producing creditable and auditable data. These were informed by the research aims, substantive literature, and the outcome measure used within the RCT results.



The participant interview schedules were based on the determinants as proposed by the Ottawa decision support framework (O'Connor et al., 1998). The questions examined a participant's; knowledge, clarity of information needs, support, expectations, personal resources and role in treatment decision making. This same framework was applied in the selection of outcome measures for the RCT, this directed the interview to elaborate on topics measured quantitatively. In developing the participant interview guides formal piloting was not undertaken however the content and question formulation was shaped and explored in consultation with expert patients. The same interview schedule was used for all participants. However, for intervention participants there were prompts to further discuss the specific elements of the intervention. The interview schedule for clinician's evaluated the intervention materials (Consultation plan, audio recording, summary) and the impact on; their patient, the consultation and their style of consulting, in addition it examined how relevant the intervention was to their practice. The same schedule was used for both cohorts of clinicians. Strategies employed during the interviews included use of different types of questions including those that gathered information about experiences, explanations, opinions, and emotions. Other techniques also included use of descriptive grand tour questions (Spradley, 1979) where broad overarching questions were used to explore general health consultation and decision-making issues, through to funnelling down to specific questions (Kvale & Brinkman, 2008).

Patients with cancer can be perceived as a vulnerable group (Hawryluck, 2004), with qualitative research interviews having potential to evoke strong emotional responses. It was therefore understandable that some patient participants wanted carers to be present when talking with the researcher. Whilst this was not part of the original study design, a decision was made to accommodate paired interviewing. This approach is not known to inhibit data

collection about sensitive issues (Morris & Thomas, 2001), and indeed can bring a different understanding. Therefore some interviews were joint interviews where both patient and carer were present and where the researchers was responsive to the needs of both participants (Morris & Thomas, 2001).

### **7.7. Data collection**

As reported above, two interview schedules were developed as a guide for each interview (all patients and clinicians). Any new issues identified in the early interviews were incorporated into the schedule for subsequent interviews. All interviews concluded by asking whether the participant had any questions or whether there was anything else to add to the interview.

Interviews were conducted at the participant's house, at the primary study site, or over the telephone. This was directed by participant preference and convenience. Prior to commencement of the interview, participants were reminded of the purpose of the interview and their right to withdraw at any time, whilst assuring confidentiality and anonymity during the study processes. The interview schedules were used to guide the conversation and ensure all topics were covered with each participant, whilst also remaining open to incorporate new and emerging areas of importance to the participant and relevant to the study.

All interviews were recorded with the participant's consent, using a digital audio-recorder to obtain an accurate record of what was said. The recording provided a complete account of the individual's responses, thereby increasing data reliability by reducing the selective filtering of data through personal recall and summation (Holloway, 2005).

## **7.8. Qualitative data analysis**

A wide range of literature documents the underlying assumptions and procedures associated with analysing qualitative data. For this work, the main approach used to manage, organise and interpret the data was framework analysis.

Many established qualitative data analysis approaches are associated with specific approaches or traditions, such as grounded theory (Strauss & Corbin, 1998), phenomenology (e.g., van Manen, 1990), discourse analysis (e.g., Potter & Wetherell, 1994), and narrative analysis (e.g., Leiblich, 1998). The framework methods sit broadly within a category of thematic analysis (Pope, Ziebland, & Mays, 2000).

Framework analysis was used as it is suited to research with specific questions, a pre-designed sample and apriori issues to be addressed, as was the case in this thesis (Ritchie & Spencer, 1994). Although framework analysis can be used to generate theory, its prime use in this study was to describe, organise and interpret what was happening in a particular setting. In undertaking this, the process of analysis and the findings are set out to be accessible and transparent to others outside of the analysis team, thereby enhancing study rigour (Pope, Ziebland, & Mays, 2000).

Qualitative data analysis is essentially about discovery, in which the tasks; categorising, theorising, explaining, exploring and mapping, are all fundamental to the analyst's role (Ritchie and Spencer, 1994). The framework analysis method facilitates the completion of each task. Although framework analysis uses grounded and inductive analytic approaches, the analysis starts deductively from pre-set study aims and objectives. The framework method provides a highly systematic way of categorising and organising data and is

ultimately used to produce structured summarised data. In this way, the method facilitates the constant comparative technique (Strauss & Corbin, 1998) which was used to refine themes, through the constant review of data across the matrices. As this study involved three cohorts of data this method supported the comparison across experiences at the interpretation level.

Prior to the start of data analysis, all digital recordings were professionally and confidentially transcribed. Transcriptions were re-read for accuracy and anonymised through the removal of names and places mentioned throughout the interview. Transcribers were offered a debriefing session as transcribing interviews in this area is recognised as an emotional burden (Kendall et al., 2007). Once transcribed, data analysis commenced.

Qualitative analysis was undertaken following Ritchie and Spencer's principles of framework analysis (1994). This is a five stage matrix method of familiarisation that develops a thematic framework through indexing, charting and finally mapping and interpretation. All participant data was analysed together (CRC and HGG). Clinician data were analysed separately with a separate thematic framework. Two researchers conducted the analysis, the author of this thesis and an independent researcher (MC) not familiar with the trial but with expertise in qualitative analysis. The roles within the analysis are described in each of the five stages of analysis. Details of how each of the five stages were accomplished in this study are now given (exerts are also provided in the appendix 23 & 24):

- 1) Familiarisation: In this phase of the analysis all transcripts were read several times and annotated thoroughly on encrypted word files. Key ideas, issues and possible themes were noted and the relevant text highlighted. This was an immersive time which helped develop an awareness of potential repeating patterns throughout the data. The researcher became familiar with one data set at a time (HGG, CRC intervention, CRC control, and in the next wave of analysis, clinicians).

2) Developing a thematic framework: Through familiarisation, gradual development and clarification of the important common themes emerged. Through conversation with another researcher (MC) who read a sample (20%) of each cohort's interviews, broad key themes and subthemes were identified. These were numbered to create a thematic framework, and applied to six patient transcripts (2 control and 2 intervention, 2 HGG) and 2 clinician transcripts. In being responsive to the text, this process refined themes, redefined categories and ensured all relevant issues and conceptualisations encapsulated the experiences and attitudes of participants. Through this process of constant comparison and checking to see if the theme categories accurately captured experiences, researchers discussed, deliberated and agreed upon a final thematic framework to sort the data. Two researchers (author and MC) were involved in this process.

3) Indexing: The finalised thematic framework index was systematically applied to all transcripts. It was preferable to keep the same index for different patient groups (control and intervention) as it facilitated the identification of common and divergent themes. Text within the transcripts were highlighted and annotated in the margins with the corresponding index number. Two researchers took part in this process. The process of making judgements is subjective. However, in checking with another researcher (MC), this made the processes visible to others and, through the annotation of transcripts and charting of quotes, is therefore open to scrutiny. Five transcripts (1 control and 1 intervention, 1 HGG, and two clinicians) were indexed by both researchers who then came together to compare coding. Again, a process of deliberation and further refinement of the description of the categories took place. One researcher (author) then continued to index the remainder of the transcripts. Multiple indexing [where single passages contained a number of different themes] were noted for later stages of analysis.

4) Charting: Within the charting stage for the participant data four charts were devised for each of the major themes that emerged, informed by the thematic framework. For the clinician data three main themes emerged and so three charts were created. Participant's quotes were lifted from the corresponding transcript and entered into the relevant chart, along with their assigned study code and the transcript line number. This stage resulted in four tables of relevant quotes from all participants (HGG, CRC control and CRC intervention) and three for clinician data. Two researchers reviewed the charts to further ensure the quote represented the category. If there was no agreement about the representativeness of a quote, it was removed.

5) Mapping and Interpretation – Researchers returned to the key question of analysis and systematically reviewed each chart to map and interpret the data as a whole. Experiences and accounts were compared and contrasted, salient patterns were searched for and explanations sought.

Although the analysis process employed the approaches of interpretation; identifying patterns, constant comparison and the exploration of conceptual and thematic linkages, the nature of different populations added a layer of complexity. A further complication arose from there being no set procedures that supported the analysis of qualitative evaluation across different sample populations. It was important for the rigour of the interpretation phase that the data analysis was guided by principles to distinguish the similarities and differences within and between groups (HGG, CRC control, CRC intervention). Consequently, a framework broadly based on Lewis's (2007) framework for analysing longitudinal qualitative data was applied to provide structure to the analysis (only stages 2 and 4 were relevant to, and used for the analysis of the clinician data):

1. Isolated individual group analysis: looked at the cases within each data set in isolation of the other groups (HGG, CRC control, CRC intervention).
2. Within population analysis: explored the experiences of receiving care for colorectal cancer from the perspectives of the intervention and control groups. Explored the experience of delivering care from the perspective of the CRC clinicians separately from the HGG clinicians.
3. Within intervention analysis: enabled the exploration of the experiences of Navigation between the two different populations (HGG and CRC intervention) to explore similarities and differences in the different contexts.
4. Comparison across groups: to explore key issues, similarities and differences in experiences across all the participant groups.

Within the comparison across groups it was important that the control group were fairly and accurately represented and not swamped by the intervention data. Careful consideration of this was utilised throughout the interpretation phase and guided the write-up of the themes to represent the control experience first followed by the contrast with intervention participants. When selecting quotes to represent participant's experiences, it was important and integral to the quality of the research to not use quotes that would only represent the interventions qualities. This integrity was maintained through constant checking that identified quotes best representing saturated views as verified during the indexing stage through conversation with another researcher.

## **7.9. Quality in qualitative research**

Given the interpretative nature of qualitative methodology, it can be challenging to assess if high quality research has been accomplished. A method that reliably assesses the rigour of qualitative research has not been fully agreed upon. One of the main criticisms in this area of rigour is that observations and interactions are open to the subjective interpretations of the researcher, and thus are unscientific (Hammersley, 1998). Furthermore, it is argued that if research cannot be replicated, then it is unreliable (Atkinson & Silverman, 1997). The challenges of how a framework may reliably assesses the quality of qualitative research has resulted in many approaches being developed and much debate over which approach holds primacy (Shenton, 2004). Consequently, criteria used to assess the quality of qualitative research is numerous, and often contrasting (Dixon-woods, Shaw, Agarwal & Smith, 2004). Additionally, there has been concern that criteria to assess quality may stifle the interpretative and creative nature of qualitative research (Schwandt, 1996). Debates about whether criteria should exist are concerned with researchers resorting to ‘quick fixes’ to comply with evaluators’ needs (Barbour, 2001) However, as qualitative methodology is increasingly being regarded as an important method in furthering empirical understanding (Greenhalgh et al., 2016), there is need to appraise the quality of qualitative research.

In this study, specific strategies were adopted to review the rigour of this research. Several works that critiqued the quality of qualitative study and qualitative evaluation were used to make assessment of study rigour. These combined the Dixon-Woods et al., (2004) paper that, in appraising qualitative research, proposed a list of prompt questions, with the Spencer, Ritchie, Lewis & Dillon’s (2003) framework for assessing qualitative evaluation. From Dixon-woods et al.’s (2004) work, a number of questions were applied to the design and conduct of this study in order to assess study rigour (p.224) including:



- Are the research questions clear?
- Are the research questions suited to qualitative inquiry?
- Are the sampling, data collection and analysis clearly described? Are they appropriate to the research question?
- Are the claims made supported by sufficient evidence?
- Are the data, interpretations, and conclusions clearly integrated?

These broad questions were integrated within the framework for appraising the quality of qualitative evaluation by Spencer et al., (2003). This framework was created to appraise published work, however it was also useful to apply to the design and conduct of this research as the study progressed. Spencer et al. (2003) suggests four central principles underpin the quality of qualitative evaluation: contribution to knowledge; defensible design; rigour in conduct (through transparent collection, analysis and interpretation of data); and credibility in claims. As there was some overlap between this framework and the framework proposed by Dixon-woods et al. (2004), relevant items to specifically appraise qualitative evaluation research were chosen. Four of the original eighteen questions proposed by Spencer et al. were deemed relevant to the evaluative nature of this study and were applied to further guide the rigour and trustworthiness of conclusions (2003, p.9-15):

- How well does the evaluation address its original aims and purpose?
- How credible are the findings?
- How clear is the basis of evaluative appraisal?
- What evidence is there of attention to ethical issues?

These questions were used to address issues of trustworthiness: credibility, transferability, dependability, and confirmability (Lincoln and Guba, 1985). These are now discussed in more detail.

To ensure credibility of the study, the method was purposefully selected to best describe experiences of participants in the key areas. Triangulation of data across and within the groups, thereby cross-checking data sources, added to the credibility of the study. The relationship with participants over time meant that re-visiting issues raised in earlier interviews (although not reported here) was feasible and further reinforces the study's credibility. Using a comparative method within the analysis to example multiple data sources meant that developing analytical ideas could be tested (Silverman, 2013). Use of thick description in the data and data write up was also important to allow assessment of whether findings were reflective of the data presented. Peer review was regularly undertaken during data analysis with another researcher, and when presenting at research seminars and conferences. As highlighted by Shenton (2004), such opportunities provided valuable feedback and fresh insights into the analysis and findings.

Although findings from this study do not claim to be representative to other populations and settings, identifying the transferability of the research findings to wider audiences is an important issue. However, it is for the reader to determine, based on the contextual information provided, and the details of methodology and methods used, the extent to which findings here can be applied to other settings. The in-depth detail regarding the context and methods also assists in the assessment of dependability (reliability in quantitative research) in this work.

Confirmability addressed the extent to which the researcher has influenced the study. In rigorous qualitative research, researchers must represent participants' perspectives in a credible and dependable way whilst acknowledging any possible influence of their presence. In this study, this has been addressed in three ways: triangulation, audit trail, and reflexivity. Triangulation is a means of reducing researcher bias and has been outlined above. Providing sufficient detail for others to undertake the study and keeping records as audit trails assist in making clear the research procedures and research decisions made. This was facilitated by the use of framework analysis which provides a clear audit trail through the five stages of analysis. Finally, being reflexive, as discussed in the following section is the final strategy used to ensure confirmability of the study.

The detail and content given through all methods and findings chapters, and exploration of this study in the discussion chapter has been provided to act as evidence to assess whether these areas have been suitably addressed.

#### **7.10. Reflexivity: The role of the researcher**

Within qualitative research it is acknowledged the researcher is a central figure who influences, if not actively constructs, the collection, selection and interpretation of data (Finlay, 2002). The researcher therefore needs to reflexively recognise that they are part of the social world being researched (Gobo, 2008). Undertaking such reflexive practice requires the researcher to critically consider the nature of the relationship held between the researcher and study participants and how the researcher role is made explicit during the research (O'Reilly, 2009). Reflexive practice also requires consideration of whether or how the researcher has influenced study processes and the final written product (Bradbury-Jones, 2007). In this study this required review as to whether any researcher bias was introduced

into the research interview or reporting on the impact of the Navigation intervention. Such reflexive practice and making transparent the reporting of the research process were perceived as integral to the rigour and validity of the study findings (Allen, 2004).

In recognising and upholding the principles of reflexivity, throughout the thesis, I recognised the effect I could have on the research process, data collection and data analysis. Prior to commencing this PhD, I had undertaken research requiring interviewing and collecting survey data about information needs within a general oncology population. However, as a junior researcher I had limited experience of research within a group of people acutely aware of their mortality. In order to maintain a robust method of data collection, I recognised I needed to be aware of how interviewing someone with a life-limiting prognosis affected my questioning. As an interviewer, I grappled with the dilemma that participants were spending their limited time talking with me about their experiences of the intervention. I recognised this dilemma had the ability to negatively impact the collection of data, for instance making me hyper sensitive to participants' needs, and in the analysis of data whereby the pressure of accurately representing a person now deceased, weighed heavily. Acknowledging these thoughts, I sought advice and counsel early into my PhD from two senior researchers, expert in end of life research and who had previously conducted research into how researchers manage data collection in this area. The resultant conversations highlighted to me that often such qualitative interviews were useful for participants (Kendall et al., 2007). I therefore conducted these interviews sensitively, always commencing the interview with 'tell me what has happened up to now / since we last met.' This gave the participants choice about what they would like to tell me. This helped me to undertake the interviews respectfully but maintaining focus on the aims of the research and to capture the experience of Navigation from the perspective of the individual.

In undertaking qualitative evaluation research, the burden of asking the ‘right’ questions to uncover the mechanisms of what was happening was challenging; compounded by the fact this was a funded study. There is a tendency for the gathering of qualitative research to become self-indulgent and so the frequent de-brief with others on the research team was integral to maintaining an objectivity to the collection of data

#### **7.11. Ethical considerations and Qualitative research: conducting ethically sensitive research**

Although qualitative research does not generally place participants at risk from procedures, they may be exposed to data collection that is both intrusive on and invasive of sensitive experiences. Ethical issues are potentially heightened in research with people who are potentially vulnerable, and with a diagnosis that may be causing physical and mental deterioration, such as HGG (Lawton, 2001). In interviewing about experiences of cancer, awareness of ethical and sensitive issues is paramount and flexibility in technique is required (Morris & Thomas, 2001). Balancing the benefits of discovery against the potential risks to the informant was an integral consideration throughout data collection. Given that some participants may not understand or wish to be confronted with their prognosis, Murray et al., (2009) suggests researchers should proceed as if people do not have awareness of their disease and prognosis, unless explicitly acknowledged otherwise. Within the interviews cues about willingness to discuss end of life issues were responded to rather than asked about directly.

Full details of the consent and capacity issues in this study have been detailed in Chapter 4 section 4.5.: ethical approval, data management and study funding. The specific issues of informed consent and competence were considered when arranging and conducting the

research interviews. It could be argued that the qualitative design of the study may render informed consent impossible as the direction and content of the research interview is, to a certain extent, unforeseeable. Participants were asked to re-confirm their consent at the beginning of each interview (Kendall et al., 2007) and at the end of the study, to ensure that fully informed consent for analysis on the data generated was gained. Capacity for consent was continually assessed in collaboration with the patient's health care team. If capacity diminished such that the patient's main carer was taking responsibility for their care decisions, carers were asked if they would like to continue using the intervention. Carers in this instance were defined as someone who shared the experience of cancer with the patient (Morris & Thomas, 2001). If any of these conditions were not fulfilled, the patient was withdrawn from the study.

Researchers have responsibility for the safety of their participants whilst collecting data and this is another important aspect of moral and ethical decision making. It was essential to ensure that participants were not caused any distress by participating in the study.

Rescheduling interviews due to symptoms and/or carer gate-keeping was handled with sensitivity, and opportunities to withdraw from the study were reiterated at several points (Kendal et al., 2007). It was also important to know how to bring interviews to an end in a manner that left participants in a safe emotional state with access to external counselling support if needed (Kendall et al., 2007). Techniques such as normalising the situation and bringing patients back to the present, with questions such as 'what are you doing for the rest of today?' were used to draw interviews to an end. The nature of data collected during qualitative interviews is usually more intimate compared to that disclosed during normal social discourse; this can pose a dilemma for the researcher who must then decide whether

such data is kept private or included as research data. All participants were assured of their anonymity throughout the interviews.

The ability to establish trust, maintain a fine balance between objective and empathic listening and taking of a non-judgemental stance were identified by Cowles (1988) as key factors in eliciting information from participants during an interview; and these remain relevant today. I reflected on one interview where a participant had talked at length about losing her husband and her job. Reviewing the transcript, I wondered why I had not ended the interview earlier as I had enough information. I reflected that I had let it happen because the participant had provided information that was important for me, and having done that she was entitled to talk about what was important to her. Although this approach was intuitive, it is further justified by this quote which aptly speaks to the dilemma I faced: “Egalitarian research is more likely than researcher domination, to allow participants to talk about what is important to them, express emotions in a spontaneous fashion and act in ways that have meaning for them rather than in way perceived to be desired by the researcher.” (Hall & Stevens, 1991, p.25)

#### **7.11.1. Researcher Welfare**

In terms of researcher safety during the off-site interviews, the researcher informed a third party of the time and place of interview. This offered protection to the researcher as a lone worker, whilst preserving confidentiality of the participant. The researcher telephoned the Navigators prior to the interview beginning and again once it had finished. This kept the researcher safe.

The responsibility of the researcher for participant welfare was also significant, particularly within this patient group. Relationships with the intervention participant group (CRC and HGG) were inevitable, cultivated over time by multiple contacts and visits. While professionalism was maintained at all times, there were times where it was difficult to switch off from distressing events. As noted for the Navigators in chapter 4 section 4.6.4, the role of de-briefing sessions were also important for the researcher. The use of an interview journal helped me to reflect and provided a written outlet to express any concerns. Whilst such responsibility cannot be taken lightly by researchers in this field, it should be noted that interactions with this patient group, and conducting interviews which address sensitive and distressing subjects, although demanding, can be satisfying, humbling and at times, inspiring (Kendal 2007).

## **7.12. Conclusion**

This chapter has described the qualitative study design to evaluate Navigation with CRC and HGG participants and their consulting clinicians. The design utilised qualitative research interviews to best answer the research questions posed by this thesis. Chapter 8 will present findings from the patient interviews and Chapter 9 will explore the perspective of clinicians on the use of Navigation.



## **Chapter 8: Qualitative findings of the patient's perspective**

### **8.1. Introduction**

The previous chapter has outlined the qualitative methods utilised in this evaluation study. This chapter will describe participant's experiences of their oncology consultations with clinicians over the course of their treatment, particularly focusing on aspects of decision making and information exchange. All participants retrospectively reported their experiences of the three (in some cases four) consultations attended over the previous six months. In this, comparison is made of the experiences of Navigated consultations between HGG and CRC intervention participants. The experience of usual care as reported by CRC control participants is also explored.

### **8.2. The sample**

#### **8.2.1. The colorectal (CRC) sample**

Twenty-four trial participants were invited to take part in the interviews, seven declined. Seventeen interviews were conducted with trial participants (8 intervention, 9 control). This sample included 11 males (57.9%) and 6 females (54.54%), with an age range of 39 – 75 years (M 60.2, SD 9.2). Details of participant characteristics are shown in Table 8.1.

All interviews were conducted within one month of the treatment ending. At this stage participants were mainly well, particularly those who had treatment with curative intent, and their illness did not dominate their lives. All participants in the intervention arm were navigated 3 times; the initial consultation to decide treatment, mid-way through to review treatment and following the end of treatment.

**Table. 8.1.** Characteristics of CRC trial participants interviewed.

Pseudonym	Trial arm	Gender	Age (years)	Treatment intent	Location of interview
John	Navigation	Male	61	Curative	Phone
Amy	Navigation	Female	52	Curative	Phone
Brian	Navigation	Male	66	Curative	Face-to-face
Angus	Navigation	Male	69	Curative	Phone
Daniel	Navigation	Male	59	Palliative	Phone
Phil	Navigation	Male	61	Curative	Face-to-face
Jan	Navigation	Female	75	Curative	Phone
Rose	Navigation	Female	39	Palliative	Face-to-face
Bill	Control	Male	51	Curative	Face-to-face
Mike	Control	Male	57	Curative	Phone
Ian	Control	Male	51	Palliative	Phone
Barry	Control	Male	59	Curative	Phone
Jill	Control	Female	52	Curative	Phone
Susan	Control	Female	72	Palliative	Face-to-face
Alex	Control	Male	70	curative	Face-to-face
May	Control	Female	65	Curative	Face-to-face
Jeff	Control	Male	65	Curative	Face-to-face (paired interview)

### 8.2.2. The High Grade Glioma (HGG) Sample

Serial interviews (n=3) were conducted with each HGG participant to evaluate the intervention. To facilitate the comparison of experiences across the oncology populations (HGG and CRC) only the final interview, following end of treatment, with HGG participants was included in this analysis. Final interviews were conducted at a similar time point as colorectal participant interviews, within one month of ending initial treatment. HGG participants who were interviewed at this time point were re-adjusting to life without frequent hospital intervention.

Seventy three participants were assessed for eligibility, 51 were invited into the trial. Twenty participants consented for the Navigation study. Eleven participants were interviewed at this final time. Nine of the original cohort were not interviewed at the time point due to; death

( $n=4$ ), experiencing a physical or mental decline ( $n=4$ ), and discontinued participation in the study due to geographical re-location for further care ( $n=1$ ).

Participants interviewed included five males and six females, with an age range of 29 to 69 ( $M51.55$ ,  $SD13.03$ ). The majority of participants ( $n=9$ ) were diagnosed with a Glioblastoma (GBM), this is a grade four brain tumour with a prognosis of 18-24 months. Two participants were diagnosed with an Anaplastic Oligodendroglioma, a stage three brain tumour with a prognosis of 5 years. Both are categorised as High Grade Gliomas (HGG). In total 15 people were interviewed as four participants opted for paired interviews, with their husband ( $n=2$ ) or wife ( $n=2$ ). This was deemed useful and not limiting in the interview as discussed in the methodology (Chapter 7 section 7.6). Details of participants are shown in Table 8.2.

Participants on average, took part in 3.09 Navigated appointments: initial treatment planning, mid treatment review and post treatment consultation. Participants who received chemotherapy in addition to radiotherapy required one more appointment mid treatment and so were offered four Navigations. Details of these consultations have been given in Chapter 4.

**Table 8.2.** Characteristics of HGG participants interviewed

Pseudonym	Gender	Paired or single interview	Age	Diagnosis	Navigated appointments	Location of interview
Roy	Male	Single	53	GBM	3	Phone
Carrie	Female	Single	29	GBM	4	Phone
Harriet	Female	Paired	57	GBM	3	Face to face
Jen	Female	Single	39	Anaplastic Oligodendroglioma	3	Phone
Donna	Female	Paired	59	Anaplastic Oligodendroglioma	2	Face to face
Ted	Male	Single	69	GBM	3	Phone
Rod	Male	Single	68	GBM	3	Phone
Mick	Male	Single	47	GBM	4	Face to face
Claudia	Female	Single	34	GBM	3	Face to face
David	Male	Paired	56	GBM	3	Face to face
Pam	Female	Paired	56	GBM	3	Face to face

### 8.2.3. Total participant sample

The total sample of participants included in this analysis consisted of twenty-eight people, sixteen males and twelve females, see table 8.3 for details. Nineteen of these participants were exposed to the Navigation intervention, nine received usual care. Description of usual care and the Navigation intervention are detailed in Chapter 4, however, a brief description of the intervention is included in table 8.4 below.

**Table 8.3.** The demographics of the qualitative participant sample

Demographics	CRC control (n=9)	CRC intervention (n=8)	HGG (n=11)
Age	M 60.25, SD 11.02	M 60.22, SD 8.14	M 51.55, SD 13.03
Gender			
Male	6	5	5
Female	3	3	6

All interviews were conducted within one month of a participant's end of treatment review appointment at the clinic. The interview data generated from the two cancer population cohorts (CRC & HGG) were analysed separately. Analysis of both data sets resulted in similar frameworks of experiences resulting from the intervention. For this reason the

interview findings of the CRC trial participants and HGG participants will be synthesised and presented together. The findings from the control participant interviews will be used to contrast against the intervention participants findings. Similarities in, and differences between the two oncology population's experiences will also be presented. Quotes will be used throughout to illustrate the findings, followed by the study participants pseudonym, age and trial arm group.

**Table 8.4.** The Intervention, a brief description.

Navigation elements	Details
<b>Consultation Planning:</b>	Participant and Navigator create a list of prioritised questions and important information for the consultation.
<b>In the clinic appointment:</b>	Consultation plan used to ensure questions are covered. Navigator attends the appointment with the participant to type notes and set up the recording equipment.
<b>Summary &amp; audio recording:</b>	Participants receive an audio recording of their consultation via CD and a written summary (approved by attending clinician).

### 8.3. Themes

Four overarching themes were developed from the data that described the experiences of the medical consultation. These themes are each presented and the differences between Navigated and usual care groups, and across the two cancer populations is discussed. The four themes are:

1. Preparation for consultation: This theme describes how participants planned for the medical consultation, what behaviours and activities were undertaken and the outcomes of this from the patient's perspective. The theme describes the differences between usual care and intervention participants about how time was spent planning for their oncology consultation.
2. Information exchange in the consultation: This theme describes participants' experiences of how questioning and answering occurred during the medical

consultation and the differences between usual care and intervention participants' experiences.

3. Recall and understanding of the consultation: This theme looks at the experience of having a record of the medical consultation that gives information to help reflect on, and comprehend details shared. Participant experiences of being provided with a consultation summary and audio-recording are described and contrasted to participants' experiences of usual care in which neither are provided.
4. Decision making in the consultation: This theme explores how participants felt about the decisions made and their participation in this, during the medical consultation and during their disease management. Intervention participants who underwent consultation planning and coaching and were provided with an information record, are contrasted to usual care.

To give context to the differences in participant perspectives , findings from participants receiving the intervention will be presented and then contrasted, within theme, to the perspectives of usual care participants. This structure will thereby help qualitatively evaluate the Navigation intervention in its use across and within the study cancer populations.

### **8.3.1. Preparing for the consultation**

Preparing for a medical consultation appeared to be a new concept for all participants across the study. This was particularly evidenced in the interviews with Navigated participants who reflected that they would not have prepared for the consultation without the support of the intervention. In addition, there was minimal data demonstrating preparation for the medical consultation in the control participants' interview data. Navigated participants reported

feeling supported by the intervention to prepare for their upcoming clinic consultation. This section is broadly structured into the areas of: (dis)ordered thoughts and managing anxiety.

### *(Dis)ordered thoughts*

Intervention participants reported initially feeling unable to articulate and formulate their questions prior to the consultation. The reasons for this were unclear but may have been associated with the stressfulness of the situation. However, what was evident in the interviews was that through reflection and deliberation with the Navigator in the consultation planning stage of the intervention, participants could clearly identify the cause of their concern and felt supported to verbalise their questions clearly with medical staff:

*'I just couldn't put them into the words that I wanted, I just couldn't find the words so that really helped.'* Rose, 39, CRC Navigation

*'It is helpful to formulate what you want to ask beforehand or, you know, have some help to do that.'* Jen, 39, HGG

In addition to being able to clearly formulate their questions, participants felt they were able to focus their mind to identify what the key issues were they wanted to understand during the consultation. Acknowledging the time pressures of clinic appointments, participants felt enabled to focus on the most pertinent matters:

*'It [Consultation Planning] helped me to focus my mind.'* Daniel, 59, CRC Navigation

*'It really made you focus beforehand on what it was that you wanted to talk about or the information that you wanted from the clinician, instead of just going in blank and the conversation not being focused enough and getting confused.'* Donna, 59, HGG

Through spending time with the Navigator reflecting on their situation and the information they wanted to gather in their consultation, participants appeared encouraged to consider their

situation more than they may have without the intervention: (*'It just made me think about it [healthcare] a bit more.'* Brian, 66, CRC Navigation). This meant that while knowing results of tests was very important, participants recognised the consultation provided an opportunity to ask more about the concerns on their mind, for instance one HGG participant planned to ask if his condition was hereditary. Asking these questions, which initially appeared peripheral, was acknowledged as some of the most important information gathered:

*'The most important thing is the fact that, you know, any questions you've got you can, you come out with them. So that's vital. Because if I'm honest, when you go in that room the only thing you're thinking about is, "How did the scan go?"'* Partner of Harriet, 57, GBM

The majority of participants receiving usual care had not given consideration to preparing for the consultation. This suggests the usual care experience is to arrive at the consultation without allocating time to preparing questions or important information to share with the clinician. This lack of preparation may be attributable to viewing the 'clinician as expert' as discussed in theme four later in the chapter. Two control participants reported preparing for their consultation. The internet and their partners were valued sources of support in aiding their preparation:

*'I found it difficult to ask because I found it difficult to phrase the question and I think I had looked up a website that sort of gave you questions to ask; the type of questions you might want to raise just to try and get the vocabulary right.'* May, 65, Control  
*'I jotted down things I wanted to ask, because I realise sometimes you get bombarded with information and I found it was quite good to chat it through with my wife and she would say 'oh you mentioned this, remember you were concerned about this three*



*days ago'. Because your consultations are at a specific time, but things crop up in your mind a week or a day or on the morning.'* Mike, 57, Control

### *Managing anxiety*

The space to reflect on and talk about individual situations with the Navigator, without the expectation of answers, appeared therapeutic for some participants. It provided participants with the permission to offload their concerns to someone who was not involved in their care and wouldn't be impacted by their emotions. This appeared to calm a mind that felt busy with questions:

*'It's like, you're thinking about it a little bit more, rather than just going in there and feeling that the questions are then building up in my head again.'* Carrie, 29, HGG

*'Not that I'm saying they don't care but they're not going to take it home with them, it's their job, it's what they're there for and they're not going to worry about you when they're in their bed or going out for a meal whereas my husband would.'* Rose, 39, CRC, Navigation

The consultation planning appeared successful in enabling participants to prepare for their consultation because it was a relaxed conversation, removed from the pressure and anxiety a medical consultation could induce:

*'You weren't under stress earlier on talking to [Navigator] on the phone or whatever, saying what kinds of questions we had, you'd get prompted, [Navigator] would prompt you 'do you want to ask about this, what about holidays, do you want to ask any questions about that?' and so you got all those questions out.'* Partner of David, 56, HGG

*'Well, thinking of questions before it's quite difficult for a patient, I think, to think in detail about questions. But it's useful to have some idea of questions.'* Ted, 69, HGG

Over time, participants appeared to feel reassured in knowing they would have this time with the Navigator to plan for their appointment. This pattern of preparation appeared to enable participants to engage in their own preparation strategies independently for the consultation planning appointment:

*'To me that was the most valuable, the preparation and I found that extremely helpful knowing that [Navigator] was gonna phone, made me think about it and so I was already thinking ahead, I jotted down ideas so that I felt like we had a meaningful discussion, it just helped and [Navigator] would add things and clarify things so that when I came to the meetings I felt very prepared so that above anything else was what I found really, really helpful.'* Phil, 61, CRC Navigation

Present in the HGG participants account, but not the CRC intervention, was the involvement of their partner in deliberation about the questions to ask at the upcoming appointment. For HGG participants and their partners, having this conversation, about the questions to ask in the consultation, was important to remove the risk of (primarily the patient) receiving more information than they wanted at that time. This finding is further supported by a later theme in which HGG participants report the need to pace the assimilation of information to which they were exposed. In this sample this finding was unique to HGG. CRC participants who had disease of a palliative nature did not relay this need. It was acknowledged without the intervention this deliberation between partners may not have occurred:

*'So actually, on reflection, we probably didn't [prior to intervention] articulate any really serious questions to each other [partner] because it was the unthinkable, you know.'* Mick, 47, HGG

*'If [Partner] says to me 'I don't want that question asked', you can tell her [Navigator]. Whereas if you're sitting with the clinician it's out of your mouth and he said 'I don't want that asked'.'* Partner of David, 56, HGG

Controlling the amount of information gathered in the consultation could be communicated through the consultation plan and for some HGG participants this was important to ensure they gathered enough information for them as an individual:

*'To a certain extent I didn't want to know everything but I wanted to know certain things ... But it was ideal and I think we just stuck around about six questions at them at the most.'* Rod, 68, HGG

In summary, intervention participants felt supported by the Navigator through the consultation planning process to prepare for their consultation. Reflecting on their situation with the Navigator enabled participants to focus on and articulate their concerns and questions. This time for planning appeared to promote clarity of their situation and for HGG participants it enabled communication between partners. When compared to control participants' data it could be argued that Navigated participants went into their consultation feeling more prepared for a conversation about their situation with their clinician. The next theme will explore the impact of this state of preparedness on the consultation.

### **8.3.2. Information exchange in the consultation.**

Information exchange in this theme, included the ability to ask the clinicians questions, satisfy information needs and convey information about oneself to the consulting clinician within the consultation. When prepared for information exchange the quality of two way communication, between patient and clinician, appeared improved. Within the consultation asking a question facilitated the exchange of information; the delivery of a question communicated a participant's information needs, preferences, views and concerns, and was satisfied by tailored answers from the consulting clinician. To develop this notion further, the clinician's role in information exchange and the patient's role in information exchange are discussed from the perception of the participants.

#### *Clinician's role in information exchange*

Navigated participants perceived clinicians used their consultation plan to structure information exchange. Participants reported consultants had copies of the plan in the consultation and appeared to use the plan as a checklist to ensure all the questions had been covered. Some clinicians made a point of checking questions off as they were covered. Participants considered that providing clinicians with a copy of their consultation plan increased the likelihood that they would receive high quality answers to their questions:

*'He was very good, I mean he looked at it [Consultation plan] from the start, he had it before I went into the room and he made a point as it were of ticking, you know, going through point by point and making sure that everything had been answered.'* Daniel, 59, Navigation.

*'The fact that that's [Consultation plan] going to clinicians before you get there you're more reliable to get answers.'* Ted, 69, HGG

Participants further felt their clinicians used their consultation plans to prepare for their unique information needs. Clinicians were able to answer their questions, offering more individualised information in the consultation. This in turn meant the clinician-patient dynamic felt like a partnership (*'it just brings the sides together easier.'* Pam, 56, HGG). Furthermore, the clinicians appeared more able to provide the information at a level that was appropriate for each participant, as this had been communicated through the consultation plan:

*'I have a rare neurological condition which I didn't expect the consultants to have the great knowledge of but they took a note of it and they tried to tailor the treatment knowing that there was something else going on and to a greater extent than I expected.'*  
Phil, 61, Navigation.

*'They would know, because they had it in advance, at what level to come in on the discussion.'* Partner of Donna, 59, HGG.

Writing a list was utilised by some usual care participants to help inform the clinician further about the participants' individual concerns in the hope that care received would then be tailored to their specific needs:

*'I would hand over a list of things; 'this is what's been happening to me'. I think my role is very much to let them know how I felt and they could then work out, medical experts could work out whether the treatment was appropriate or had to be monitored or changed.'* Mike, 57, Control.

Lists of questions were seen as a way of impacting on the clinician's behaviour in clinic and ensuring that certain matters were addressed:

*'When I go in with my list of questions, and I thought about them and researched a bit, and I think they respond in an appropriate way, if you see what I mean. They recognise that these are questions that have been thought through and they needed an answer and I get it.'* Barry, 59, Control.

However, if clinicians did not have time, nor space within the consultation for shared decision making, then the answering of questions became problematic:

*'What I found with the last one....they did all the telling, they didn't do the asking, you know what I mean, ... it was like they were telling you before letting you ask them the questions, you know, and then that was you, you're away.'* Jeff, 65, Control.

This resulted in participants gathering information needed through the internet or the hospital cancer charity centre to gather the answers to their questions:

*'And so I went online and three to five months, I thought right well that explains it then, maybe I'm still getting worse and it wasn't until May that I started to feel a lot better. I did find I was Googling quite a lot.'* May, 65, Control.

There was an expectation amongst participants experiencing usual care (CRC control participants) that clinicians would provide the information they needed without requiring any input from the patient. This suggested that in usual care, participants trusted clinicians to tell them what they needed to know:

*'We asked one or two things, but we didn't... you're waiting to hear from the professionals, you know, you're waiting on them telling you that your reports are good.'* Jeff, 65, Control.

*'Oh not really, no [did not prepare questions] because as far as I'm concerned I was in the hands of experts.'* Alex, 70, Control.

Control participants felt their care was impacted when they were seen at later appointments by a clinician they had not met before. This lack of continuity in care resulted in patients feeling uneasy and distrusting. Meeting a new clinician each time impacted on how confident participant's felt during the consultation (*'They can read the notes, but you do feel more confident if it's the same person who sees you.'* Mike, 57, Control). This posed a barrier to asking questions for participants who wanted to gather information from their named clinician:

*'I got an appointment to say I was seeing Dr [name], came along, and then this gentleman – nothing wrong with him, very pleasant, but suddenly it was a stranger that... And I thought, "Oh..." so I don't ask these questions. I had questions for Dr [name]. She said, "Have you got any questions?" and I thought, "No. Not for you."'* Alex, 70, Control.

In direct contrast when patients took an active role in the information exchange and were prepared to ask questions (as in intervention participants), being seen by new clinician was not a concern. Through the addition of their consultation plan to their medical notes, the consulting clinician was always aware of the information required by a participant, and this appeared to result in a sense of participants feeling known:

*'Whichever consultant you see has that info, you know, as well, so that they are already preparing a full answer.'* Jen, 39, HGG

*'The consultant changed ... she seemed to know, well she didn't seem to know, she had the summary [plan] there as well before I even said something, so, yeah, I do feel*

*that they knew me and this... they just had so much information about me that, yeah, they did understand and they did appreciate what was important to me.'* Rose, 39, Navigation.

#### *Patient's role in information exchange*

Planning for the consultation impacted on participants' perception of gathering information during the consultation, and the role occupied by the participant. Ultimately, intervention participants were more prepared to exchange and gather information (*'I felt well prepared and you know it was good to have a list of questions ready to go.'* Daniel, 59, Navigation).

In being clear about the questions to ask in the consultation, participants felt confident to articulate these (*'When you've done it all beforehand, all written down, it feels good.'* Harriet, 57, HGG). Having the Navigator in the consultation room, someone who also knew of their concerns and situation and understood their unique situation was perceived as supportive to the patient role in exchanging information through enabling participants to feel confident to ask questions and engage in the consultation process:

*'The Navigation thing gave you a little more confidence that you could ask these questions.'* Angus, 69, Navigation

*'... I think having somebody there a person that you've got to know over a period I think is the difference.'* Partner of Pam, 56, HGG.

*'She actually made me feel better, her presence being there because I knew she knew what I was thinking before I went in the room.'* Rose, 39, Navigation

Participants were aware that in order to gather pertinent information in the consultation and use their time effectively with consultants it was necessary to prioritise questions that were



important to them. If this was undertaken then participants left the clinic feeling they had satisfied their information needs:

*'Everything was... It was dealt with ... I mean sometimes you go and do it yourself. You go to the clinicians or you go to the dentist and you mention two or three things and then you come out and you think "Oh, forgot to mention that." But no, they were very thorough.'* Angus, 69, Navigation

*'I find with this Navigator thing I come out of there and because of the pre-questions, I've asked what I wanted to ask.'* Ted, 69, HGG

Consultation planning with the Navigator appeared to enable an intervention participant's information exchange and gathering skills within the appointment when compared to control participants. Asking questions within the consultation was significantly less dependent on a participant's memory as the consultation plan acted as '*an aide memoir*' (Brian, 66, Navigation) to remind participants of their questions:

*'Going into the clinicians, there's a million other things you think about asking and you never actually do, so having them down in front of the clinician to start with is, like, it's just brilliant. It really is, 'cause I'm terrible at remembering, getting everything out. So, no, it's been really, really useful.'* Carrie, 29, HGG

*'I mean you always forget to say something at a meeting anyway and you come out and you're I should have said that, should have asked that, but I didn't.'* Brian, 66, Navigation.

Participants recounted some interesting and unique experiences in which the consultation plan supported the two way exchange of information in the consultation. One CRC participant (Rose) found the consultation plan ensured important information was gathered,

even when she was unable to physically verbalise her concerns. Two HGG participants found the consultation plan helped them to remain part of the discussion with their clinician, even when discussing emotional or distressing issues:

*'My husband and I had been trying for a baby and I remember that appointment where I really needed to know what's going to happen here? I couldn't speak, as soon as I thought about it I was getting upset and the clinician was able to bring up that subject, talk about that subject without you having to actually say what it was that in my head, what needed answering.'* Rose, 39, Navigation

*'Donna: the questions form an agenda or a kind of conversation with the clinician. Partner: to have that agenda allows you to keep a vague grip on reality'* Donna, 59, HGG

When patients reflected on the Navigation consultations whilst reading through their Navigation summaries, it was evident for these participants how much information they had managed to gather. Often participants could not remember asking the question or receiving the information. However, the consultation plan was successful in assuring these outcomes without being dependent on the participant's listening and communication skills at that moment:

*'There's so much information there [summary] that I needed to know, but at the time, when I remember what state I was in, it would have been, if I hadn't had the structure I think it would have just been a shock. You know, the statement that Dr [name] made about it not being a curable condition that would have been me.'* Mick, 47, HGG.

Without any prompt sheets or preparation, participants in the CRC control group, spoke about the frequency with which they forgot to ask questions. Participants described the majority of

questions which they forgot to ask in the consultation as the ‘*little questions.*’ Interestingly, these were the types of questions often captured in the preparation phase with Navigators. Furthermore, they found questions would arise once they had left the consultation. The following quote illustrates how control participants recognised the importance of preparing their questions but found it difficult to allocate time to implement this plan:

*‘I forgot to ask her about hair loss, and they were just little questions that kept sort of ... and I thought, you should actually write down what you're going to ask when you go in, but you always think well it's all over, this is just a follow up and you have at the back of your mind things that you want to ask and then you forget about it when you go in.’ May, 65, Control.*

For participants who did make a list to inform the information gathering, including three control participants, it was clear how this facilitated the gathering of information that ‘May’ in the previous quote had found difficult to gather:

*‘The information that was most needed was how to deal with side effects from chemotherapy. It was just general helpful day to day practical information, which I think was fairly easy to obtain, when you asked.’ Mike, 57, Control.*

Another challenge within a consultation resulted when no specific information was available for participants, for example when participants were told how different people react differently to treatment. This appeared to make control participants feel as though the amount and relevance of the information gathered was limited:

*‘I couldn’t find anything interesting in it. Because as far as I was concerned I was doing a trial - I knew there was going to be side effects, and what the side effects*

*were, I didn't know. [Clinicians name] couldn't tell me, [Nurse's name] couldn't tell me, so I didn't see the point in reading anymore.' Ian, 51, Control.*

*'She says 'Obviously everybody's chemo's slightly different.' Jill, 52, CRC Control.*

In summary, this theme has explored the key issues to arise from information exchange within the consultation from the perspective of all participants. Within this theme some key differences emerged. Control participants experienced challenges in gathering the amount of information they had wanted. When a control participant prepared their questions, this overcame some challenges although a lack in the continuity of care when trusting in the experts to provide information was a barrier to information exchange. In contrast, intervention participants felt confident and well-supported to ask their questions. Remembering and asking questions was not impacted by their memory and intervention participants felt satisfied that all information had been gathered. Furthermore, intervention participants felt clinicians had prepared for their individualised consultation, tailoring the information to their needs, with an understanding of the patient's unique situation.

### **8.3.3. Recall and understanding of the consultation**

All participants, regardless of trial arm or cancer site, acknowledged the challenges inherent with trying to recall accurately all the information provided in the consultation. Factors such as feeling particularly stressed or shocked during the consultation, the impact of chemotherapy on memory, and the over-focusing on one piece of information, all negatively impacted on recall of the information provided in the consultation:

*'It's probably just the stress but it could have been as well with the chemotherapy and the chemicals there that I just did not have the memory, I couldn't remember half the things that were said.' Rose, 39, CRC Navigation.*

*'There's no way I would remember everything, you know. Your mind's just, you know, you're in shock, you know!'* Donna, 59, HGG

Recall and understanding of the consultation was important to participants in several ways. This is now presented through discussion on: Enabled to be present in the consultation, providing a safety-check, and enabling information for others.

#### *Enabled to be present in the consultation*

Participants who had access to an audio and written summary of the consultation (intervention participants) reported feeling more relaxed and focussed within the consultation as the pressure of remembering the information and questions to ask was removed:

*'Well, I think that certainly the consultations through the Navigator have made that you can actually maybe be, what's the word more relaxed at the consultation because I think if I miss something I'm going to pick it up from the tape, from the CD.'* Ted, 69, HGG

*'It means I can concentrate on other things, rather than... it's like, 'I've got to remember this, I've got to remember that.'* And so, yeah, it does make my life easier.'

Carrie, 29, HGG

*'When my part in the navigation was over I actually recorded it (the consultation) myself and I found it useful. Cause I think it made everybody focus on what they were saying.'* Daniel, 59, CRC Navigation

#### *Providing a safety-check*

Accurately recalling the information provided in the consultation was important to all participants and therefore having a record aided a precise recall of the information (*'If we*

*think what was that again? We can always run through it as well' David, 56, HGG.).* It was evident from the data that many participants were often troubled with the concern that they had remembered something incorrectly. In using the information record to check the accuracy of their memory this removed the need to contact healthcare staff for the information:

*'I thought of something, and I just wanted to make sure that I was thinking the right thing, you know. What I've been told, so go back and find.'* Claudia, 34, HGG

*'If something came into my head and I'd think "Oh, I'm sure we talked about that," I would look it up again, yeah.'* Angus, 69, CRC Navigation.

Partners of HGG participants were also concerned about any gaps in their memory or their accuracy of recall, and were able to access the information. This became particularly important if partners had adopted a caring role and were asked questions by a participant about their care:

*'I'm quite good at remembering what people say, but (participant name) would maybe say 'what have I to do about such, such a thing' and I think 'oh God, is that was she said?'. So you can listen to the CD and say 'yeah that's what she said'.'* Partner of David, 56, HGG

Equally when partners had differing impressions of the information they could use the record to check and resolve any conflicts in understanding quickly: *'Helps iron things out when two people have taken away differing impressions of what happened within the consultation.'* (Partner of Donna, 59, HGG).

Specifically, participants used the CD and summary as a memory aid and this helped them to: feel reassured they had remembered information accurately (*'It helps you to recall just*

*exactly what was said about any particular aspect and that's quite reassuring.* ' Ted, 69, HGG); gather answers and clarification as and when they were needed (*When things were getting a bit stressful I could look at that [summary] and say right I get those, the eight cycles of that, that means that that means this.* Rose, 39, Navigation); and to check the symptoms they were experiencing were expected side effects of their treatment (*'I felt really, really tired, probably about four to six weeks afterwards. And that's what they said would happen.'* Jen, 39, HGG). Overall the record appeared to be provide a sense of reassurance for participants.

As mentioned earlier HGG participants only, reported the need to pace their understanding of their situation. They reported being unable to assimilate all the information provided in the consultation. The information record subsequently enabled HGG participants to be in control of their level of understanding. It provided participants with the choice of gathering more information through reading or accepting their current level:

*'When I get the information sent back to me, I can see back over it and it just helps me understand a little more.'* Carrie, 29, HGG

*'We could only deal with it in bite-sized chunks really. It was a bad, bad time, trying to cope with all that.'* Donna, 59, HGG

*'You have to come back and look at it in wee bits when you can sort of cope – steel yourself to think about it again – “So, what did they actually say about that? What is going to happen? How's it going to...?” Is that right?'* Partner of Donna, 59, HGG

Where intervention participants were enabled to recall and understand their situation through reading or listening back to information about their consultation, control participants found it difficult to remember the information they had been provided with. (*You kind of listen at the*

*time and you hear and understand it but I think you do need the actual words that were spoken to look back at'* Barry, 59, Control). They engaged in strategies to aid their memory which included bringing along a partner or family member to listen alongside or take notes, or ask for a copy of their clinic letter:

*'I think the fact that I take my mum, and my dad sits in the car. And then when we come out, you've obviously got to tell my dad. So, between my mum and I, that kind of brings it back. So we talk about it coming home in the car, which means when I come in and I'm sitting here and I'm thinking about it, it's still kind of like fresh in my memory'* Jill, 52, Control

When a participant did not engage in any strategies to remember they regretted this later (*'No, no, no [didn't take notes] I should have, because before it was always up here but now I say, "Oh God, what did that person say?"'* Alex, 70, Control). However, for one participant once she had consolidated the information in her mind she did not feel the need to revisit the content. This was similarly found for some of the intervention participants:

*'I maybe sit and think about it for about 10 or 15 minutes, then 'Right, that's it, done. Let's get on with it'. What's the point in sitting here and worrying? And going 'What if this happens? What if that happens?' You can't control it.'* Jill, 52, Control

In contrast to the intervention group data the majority of control participants' accounts suggested they did not fully understand their situation. They appeared to be missing pieces of information that would help them to understand. It is unclear if this is due to memory, not asking the questions (as reported in the previous theme) or not being provided with the information. Not fully understanding their situation meant information was gathered from other sources, such as people in a similar situation (*'None of the symptoms were explained... I*



*picked up a lot when I was getting the chemotherapy from other people who were getting it as well.* 'Jeff, 65, Control.) Control participants appeared to frequently feel as though they were confronting the unknown. In addition, there was an acceptance that facing the unknown was an intrinsic part of having cancer:

*'I mean the biggest thing I suppose part of this is...is unknown, you know, kind of what's happened what is going to happen.'* Barry, 59, Control.

*'It's not knowing the unknown, that's a statement that I have used more in the last ten months than what I have ever used in all my life.'* Jeff, 65, Control.

*'No-one can tell you these things because everybody is different, you know, you've just got to find these things out as you go along.'* Edna, partner of Jeff, Control.

#### *Enabling information for others*

Having accurate recall, and also a written record was important to share with others as an update on events. Ensuring those close to the participant were kept informed and up-to-date was important. Having a record created by an independent body provided those unable to attend the consultation reassurance about the reliability and validity of the content (*If we come back we're not really, like, saying like how the clinician said it anyway.* Carrie, 29, HGG). An accurate record of the consultation was reassuring for those unable to attend the appointment and meant participants did not have to explain their situation entirely based on their ability to recall:

*'The other benefit I have is my two children can listen to the tape, or read the transcript and they've got first-hand information then. It's not what I remember to tell them and I think that's a great thing for them as well. I feel quite relaxed that they know as much as I do.'* Ted, 69, HGG

For some HGG participants they reported being able to share reliable and accurate information with loved ones helped them to manage family member's involvement and understanding. Ultimately they reported providing their loved ones with the summary appeared to ease their situation and reassure loved ones they understood the participants' situation, making life more manageable for participants:

*'I actually feel like it's calmed everyone down slightly. Everyone was, like, on panic and, like, 'Oh my God,' you know. But, I think that [provision of summary] has actually calmed the whole family down a bit, because it's in black and white, written down for you, do you know what I mean?' Carrie, 29, HGG*

*'Well, they would have accepted whatever we said, but the fact that they were hearing it first-hand was so reassuring for them I think.' Ted, 69, GBM*

HGG participants, in contrast to CRC participants, continued to use their summary's following the end of their treatment. This provided them with some reassurance and hope they had managed to cope with how their situation had been. CRC participants did not review the summaries at this time point and preferred not to be reminded of their situation in an effort to move on. This contrast highlights the differing nature of the disease where a CRC participant feels able to move on, a HGG participant knows inevitably their disease will recur. Again this was not present in the palliative CRC participants:

*'I don't think there would be any benefit in listening to it now. I mean I've moved on. They were very useful at the time.' Brian, CRC, Navigation.*

*'In some ways it was quite nice to read it all again and remind myself of, yes, how difficult and painful it was but, I think that helped remind me that it was quite a long time ago and that I'm still here a year later and I'm feeling better and I am better.'*  
*Mick, 47, HGG.*

The majority of intervention participants preferred the written summary of the consultation and not the CD. Participants felt the written summary was an accurate and reliable record of the consultation and so the need for the CD in addition was minimal. Many participants reported feeling uncomfortable hearing their own voice recorded and so preferred not to listen to the recording. (*'I don't really like listening to it because I don't like my accent.'* Angus, 69, Navigation.) Although for some it was important to listen to the CD because it provided participants with the tone of how information was relayed (*'but listening to somebody speaking is different than the written word'* Brian, 66, Navigation). Moreover, locating pieces of information in the summary was much easier and faster than using the CD: (*'I just looked at the written summary and I didn't listen to the CD. I just didn't really have time'* Jen, 39, HGG). For HGG participants, listening to the CD, especially of their first consultation was too painful, (*'I knew perfectly well we were terribly upset at various points in those interviews and it's quite unnerving to hear all that. It's raw to listen to the actual tape, too raw.'* Partner of Donna, 59, HGG).

In bringing together this theme, recall of information was important and often participants found themselves searching to check remembered facts and the accuracy of memories for reassurance to understand what was happening. For Navigated participants, the CD and summary was useful for this purpose, specifically the written summary, to ensure they had accurate recollection of information provided in the consultation. Ensuring loved ones understood what was happening was also facilitated by the distribution of the summary.

#### 8.3.4. Decision making in the consultation

It is evident from the data presented so far that all participants utilised various strategies, where possible, to ensure they gathered the information needed. All participants were asked about the processes by which their treatment decisions were made. Unanimously it appeared participants perceived decisions were made by their clinicians. Consequently, findings about how decisions were made lack a certain depth of account, reflective of how participants perceived their role and their clinicians' role in planning treatment. This was particularly evident in the HGG participants' data. Acknowledging these limitations in the data, this section will present findings in order to further demonstrate how decisions were made; a primary aim of this thesis.

Most participants identified that they did not feel as though they had the responsibility for making decisions about their care. Participants reported that their clinicians, using evidenced clinical guidance, provided clear treatment recommendations:

*'Although ultimately they'll [the clinician] say 'you make a final decision', really there is no choice.'* Mike, 57, CRC Control.

*'It wasn't really a matter of choosing, it was you're confronted with a situation and you hope for the best outcome.'* Brian, 66, CRC Navigation.

*'I was told. [Laughter]. 'This is what you're having.'* Carrie, 29, HGG

Perceiving treatment decisions in this way meant the options for a participant were reduced to a binary decision: to accept the treatment, or not. This process was generally not distinguished as a decision for participants as they perceived no viable alternatives. This feeling was particularly evident if the emphasis of the consultation was weighted on the success of treatment on survival, rather than the damaging result of side effects. Many

participants, regardless of trial arm, perceived their clinician as encouraging treatments (*'She says 'it's better to be safe than sorry'.'* Jill, 52, CRC Control) in order to reduce recurrence:

*'You know and they call it belts and braces, that's what they call it, you have the operation, it took all the cancer away, this is just a wee extra.'* Jan, 75, CRC Navigation.

Participants did appreciate that treatment plans were decisions based on best practice clinical guidance and as such there was little room for negotiation and deliberation, limiting the potential for shared decision making:

*'It's the clinical judgement they make for everyone. You know, "We're going to give you radiotherapy because it's the best treatment available. And that's it.'* Mick, 47, HGG

All participants' fundamental goal within this medical experience was the eradication of their cancer, and of survival (*'I just want to survive and that's it.'* Amy, 52, Navigation).

Furthermore, all participants viewed their clinician and healthcare team as the 'experts' in knowing what was right for them. The interaction between a strong clinical recommendation, the aim of survival and complete trust in the clinicians' expertise, resulted in all participants accepting recommended treatment decisions with confidence:

*'I have to trust that they know best what's going to make sure that I'm safe in the long run.'* Mike, 57, Control.

*'They recommended that we just go forward and have the treatment anyway because that's all that can help, that's all.'* John, 61, Navigation.

However, all participants recognised they were not committed to a treatment path before having time to discuss this with their clinician, and acknowledged this conversation was important in enabling them to understand the best options for them:

*‘Going into that discussion I thought: well, you know, I’m not...at this stage...you know 100% committed to it. I want to hear what the arguments for and against are.’*  
*Barry, 59, Control.*

Although participants did not feel they had made any ultimate decisions, intervention participants did report feeling involved in the process, ultimately nothing had or could go ahead without their consent (*‘Although you’re involved in the decisions you’re going to go with what they recommend I think, it’s difficult not to.’ Ted, 69, HGG*). While the outcome may have been predetermined by the framing of the decision, slight nuances in the trial arms experiences were evident in the data. Intervention participants appeared to engage in the process of deliberation and recognised the importance of understanding why the decision was being made through asking considered questions (*‘I can get out of them what I need to know.’ Carrie, 29, HGG*). In this way some participants reported working together with clinicians about decisions:

*‘Well I did expect and got most of the time a sense of being a collaborator rather than just a recipient.’ Daniel, 59, Navigation.*

*‘I asked questions and I said, “Whatever this boils down to, I’m just asking the questions, but in the end I’ll be guided by you because you’ve got all the experience and you know exactly what’s likely to happen and what isn’t likely to happen.’ Angus, 69, Navigation.*

*'You decide on what's best for you but you are taking the guidance and the information that's provided whether you're meant to be steered in a direction or not you're going to make the best choice for you.'* Rose, 39, Navigation

Control participants also recognised the importance of understanding why decisions were being made and tried to fulfil their information needs to understand the decision but appeared less active in this process and perceived more barriers to gathering this information than reported by the intervention participants. Subsequently, it appeared control participants were left still trying to understand their situation: *'Nothing, no, it was never ever spoken, this is stuff that we're finding out that nobody's never said anything.'* (Jeff, 65, Control).

Furthermore control participants reported a level of anticipated regret in the refusal of treatment, this appeared to substantiate their confidence in the recommended treatment decisions.

*'What's the alternative? If I say no and then six months to a year down the line I'm back to where I was, with no guarantee that it won't go into the lymph nodes.'* Jill, 52, CRC, Control.

This theme has explored decision making from the perspective of the participants. It highlighted the experience of decision making was similar for both oncology groups and both trial arms. Participants perceived their clinicians provided a strong treatment recommendation and encouraged the uptake of this decision. Participants felt confident that this recommendation was made in their best interests by an expert. Between the trial arms few differences in this experience were evident. What does appear apparent is the difference between how intervention and control participants perceived barriers to gathering information in order to understand the treatment decision.

#### **8.4. Summary of Findings**

This chapter has presented the interview data gathered from the HGG and CRC participants and contrasted the experiences within and between the cohorts. Across each of the four themes, the importance of: preparation for the consultation; information exchange in the consultation; recall and understanding of the consultation; and decision making in the consultation has been explored. Within the four themes key differences between groups were identified.

All participants did not feel treatment decisions were theirs to make, although some wanted to and utilised strategies to engage with clinicians in reaching the decision. Intervention participants appeared supported to prepare for their consultation, aided to take part in the consultation to gather and exchange the required information and enabled to recall and understand information provided in their consultation. Control participants were: not supported to prepare for their consultation, although some did engage in strategies to undertake this; experienced barriers to gathering information within the consultation, such as time pressures and forgetting questions; and reported gaps of understanding about their situation.

The next chapter will present the qualitative evaluation of the intervention from the consulting clinicians. These two sets of findings (patient and clinician) will be integrated in the final discussion chapter.



## **Chapter 9: Qualitative findings of the clinician's perspective.**

### **9.1. Introduction**

Colorectal Cancer and Neuro-oncology clinicians' views about Navigation were explored through interviews. The aim of these interviews was to ascertain the healthcare perspective of: the Navigation materials and how Navigation impacted the patient, the consultation and a clinicians' practice. The relevance of Navigation within their speciality was also explored. Interviews were analysed using framework analysis as described in Chapter 7. The findings across the sample (HGG and CRC) are synthesised and presented in this chapter.

### **9.2. Sample**

Eight consulting clinicians in the colorectal or neuro-oncology clinics were approached regarding their participation in interview. All clinicians invited had consulted with a minimum of three Navigated patients over all three appointments: initial treatment decision, mid-treatment review, and end of treatment review. All four colorectal consultants agreed to take part in an interview about their experiences with the intervention. Two out of three neuro-oncologists agreed; one declined due to workload pressures. In addition, one senior registrar in the neuro-oncology clinic met the eligibility criteria and was also interviewed. One participant had worked in both the colorectal clinic and the neuro-oncology clinic during the study period and so was able to provide a perspective across the populations. Four interviewees were female, three were male. To maintain anonymity of participants, quotes will be identified by use of the numbers assigned to each clinician. Therefore C1, C2, C3, C4 are participants from the colorectal clinic, N5, N6 and N7 are from the neuro-oncology clinic.

### **9.3. The Intervention**

Much of the clinicians' evaluation of Navigation was based on their views regarding the consultation plan (CP). Conceivably, this is because the CP is the element of the intervention that most impacted on the content and process of a clinician's consultation. To put Navigation into context, the points below are made to identify how Navigation impacted on a clinician consulting with an intervention patient:

- A patient's Consultation Plan was emailed to the consulting clinician in advance of the clinic appointment.
- A hard copy of the Consultation Plan was attached to the patients' medical notes for a clinician to review before their meeting.
- Clinicians received no formal instruction about how to integrate the Consultation Plan into their consultation. Previous studies of the same intervention had occurred at the study site and so informal conversations with breast and prostate cancer clinicians may have informed their practice in this study.
- The Navigator attended the appointment with the patient to type summary notes and audio record the consultation.
- Clinicians were subsequently sent the written summary for review before it was sent to the patient.

### **9.4. Findings**

Data from the clinician's interviews evaluating the intervention were categorised, utilising framework analysis, into three main themes:

- Usefulness for patients: reports the perceived benefits and potential disadvantages for intervention patients from the consulting clinician's perspective and is explored through the sections: preparing for the consultation and record of the consultation.

- Acceptability for clinicians: describes benefits and drawbacks of consulting an intervention patient when compared with usual care patients. The areas explored are: using the consultation plan and impact on time.
- Sustainability: explores the relevance of Navigation to each speciality and the implication for resources needed to sustain the intervention in its current model and is detailed as: acceptability within the service and feasibility within the NHS.

#### **9.4.1. Usefulness for Patients**

This theme examines clinicians' views regarding the impact on patients of preparing for their consultation, receiving a record of the consultation and the most relevant appointment for the intervention.

##### *Preparing for the consultation*

All participants reported that by engaging in consultation planning and generating the consultation plan (CP) the patient was more likely to have all their questions answered. Clinicians all made an effort to use the CP with the patient and cover all the documented questions. To ensure a patient's prepared questions were covered, clinicians used the CP as a checklist at the end of the consultation:

*'Now I tend to read it (CP) in advance to try to remember to cover the topics and then check with the sheet and the patient at the end that we've covered everything' C4*

Clinicians recognised that through this preparation stage, patients had certain information expectations of the consultation that needed to be met. Neuro-oncology clinicians reported this process of preparation was beneficial to patients as it ensured the consultation met a patient's personal goals of information gathering:

*'I would read through the consultation plan to make sure that we cover everything the patient expects to cover.'* **C2**

*'I think that's the main benefit that patients are going to get all of the information they want, out of the journey and this is going to put it into their language and kind of meeting what they want from their consultation.'* **N6**

Neuro-oncology clinicians identified that consultation planning appeared to enable patients attending the consultation to be more prepared for a discussion about their healthcare situation (*'They were sort of perhaps just a little bit better prepared.'* **N5**). Through the process of formulating their questions and concerns beforehand, clinicians suggested patients appeared more at ease with letting the consultation flow, knowing their questions would be answered:

*'I think where it helped was that it stopped patients from perhaps leaping straight to a question that was not appropriate because they knew that all the questions had been given and so they were more prepared to go with the flow with the consultation, um whereas sometimes people who haven't done that come in, they'll ask, they'll start off straight away with questions that are not really relevant at that stage.'* **N5**

For two colorectal clinicians however, some patients were perceived as not engaging in the process. They reported meeting patients who did not want to ask questions but felt, because of their study participation, that they should. Those not wanting to ask questions were categorised by clinicians as patients who ultimately wanted to be guided by the clinician about decisions:

*'There are some patients who will sit there with the consultation plan, ticking it off.*

*And there are other patients who come in and, you know, say 'Well I had to put something down. And some patients who don't look at it at all.' C1*

*'There have been a few patients who just haven't particularly wanted to engage with it at all and they're the type of patients who, by and large just want to be guided to what to do and get on with it.' C4*

One colorectal clinician felt Navigation might be detrimental to a patient's emotional wellbeing, potentially heightening the anxiety levels through pressurising those who did not wish to ask questions:

*'I think it can raise anxiety levels in patients who are already anxious and sometimes can be a bit artificial for patients who really don't want to ask questions, but feel obliged to ask questions.' C1*

No other participant interviewed commented on the impact of the intervention on wellbeing.

#### *A Consultation record*

All clinicians thought that it was useful for patients to be provided with a record of their consultation (*'I think the summary is very useful for patients.' C1*). The information record was unanimously perceived as the biggest benefit of the intervention for patients:

*'I suppose the advantages is that it they get then a record of their consultation.' C4*

*I think it is probably useful for the patients. ... The summary provided is a very accurate summary and usually covers all the points.' N7*

Most clinicians suggested patients would prefer the summary over the audio recording. The summary was viewed as a succinct record of the key information points without the small talk inherent in consultations. It was suggested listening again to potentially distressing news via the recording may be upsetting for patients. However, one clinician was aware patients had shared their recording with family members who could not be present at the consultation:

*'I know some patients actually don't want to be listening to it again, brings it all, you know particularly if it's been a bad, bad news consultation, it's quite hard for them to hear that again.'* C3

*'Because there's always there's, there's lots of chat round about the subject as well, that lots of patients don't really need to focus on, just in terms of trying to relax a patient, things like that, there's lots of chat out with the important stuff.'* N6

It was also highlighted that recording of the consultation sometimes occurred as part of routine consulting practices:

*'Some patients ask to you know record their own consultations anyhow, out with navigation... And that's their choice, but anyone can do that.'* C3

Additionally, the intervention provoked thoughts about how current practice could be improved through routine sending of clinic summary letters to patients, although it was recognised that extra resources would be key to implement this:

*'I know in some places we copy letters to patients - that's something we have talked about lots and I think you would end up in oncology writing two letters, to, from the clinic, one for the patient and one for the GP. And again we are just not resourced to put that amount of time in.'* C1

A concern arising from the use of Navigation was regarding risk of litigation. One clinician reported that less experienced medical staff were deterred from consulting with Navigated patients as they would receive a recording of the consultation:

*'Some of the junior doctors have been put off seeing patients who have been navigated, because of the anxiety of it will be taken down and used in evidence. We try to reassure them, but it can be a bit disconcerting, particularly in this day and age, with patients who are some patients take notes, and it can make you feel quite on edge because gosh am I going to say something, and if you're junior and you're still learning you worry about saying something that, you know, is not 100% accurate. And you get, 'but so and so said, he said she said'. So it can occasionally inhibit the juniors on the team seeing patients who are navigated.'* **C1**

However, it was suggested that recording the consultation in this way could help clarify for patients and clinicians where information gaps were due to memory or lack of provision:

*'Because patients often say they haven't been told something. And I mean if there is this sort of process, then we know that they have actually been told it and so that might be helpful, that might stop misunderstandings in the future. But yeah, we don't know what the patient's agenda is fully when they come to the clinic and I think the navigators do find that out.'* **N7**

*'Sometimes none of us know what the patients take on board, but at least if it's written down you know that it's been said, but the patient may not have picked that up.'* **C3**

As part of the study, patients were 'Navigated' for three oncology appointments; initial treatment discussion, mid treatment review and end of treatment. Clinicians all agreed the intervention was most useful for patients at their first oncology appointment, when treatment

decisions were made. The mid-treatment review appointment was seen as the least useful time point for patients to be 'Navigated'. When undergoing treatment clinicians reported patients had many opportunities to ask their questions, this resulted in less perceived need of the intervention for the mid treatment appointment:

*'I'd say you could argue that the most important appointment is the first one, where decisions on treatment are made. I've not found the subsequent navigation particularly useful.'* **C2**

*'I'm not sure about the mid treatment, because eh, patients are going to be reviewed during treatment anyway so any questions they have will be picked up.'* **N6**

One colorectal clinician proposed the last appointment, after the completion of treatment, may also be useful for patients to be Navigated. This was an appointment where information was given about what was next. Most notably there were no informative documents to support patients through this transition point:

*'End of treatment, when we're saying what's next, in particular when they are going to nurse led follow up after the end of actual treatment, can be quite useful we don't have a lot information about that 'what next' step and what to expect and what not. So I think at that point the summary's quite useful and I do wonder whether there's scope for a "You've finished you're treatment, what now?" booklet.'* **C1**

Neuro-oncology clinicians also supported the opinion that there was most need for the intervention at the first consultation, as opposed to follow-up consultations. This was ascribed to the distressing nature of the information provided during the first neuro-oncology consultation and the impact of this distress on the patient's memory:



*'A lot of our patients don't recall a lot of what's said in the um, consultations so I suspect they're probably more useful for new patients rather than the follow up patients. Cos often the new patients are the ones that are distressed and don't really remember a lot of what's been said.'* N5

#### **9.4.2. Acceptability for Clinicians**

This theme explores how acceptable clinicians found the intervention when integrated into their usual clinic time. It examines the clinician's perspective regarding how the intervention impacted the process of the consultation, the patient and their time. All clinicians, when asked, reported that they were comfortable with the Navigator being present in the consultation room.

##### *Receiving the consultation plan*

Receiving the consultation plan prior to meeting the patient was viewed by all clinicians as beneficial. This plan gave clinicians an awareness of what the patient knew and wanted to know:

*'The pre-consultation plan at least gives you an idea what the patient knows when you come to the first consultation. That's been useful.'* C2

*'You get a better idea of patients' baseline understanding. And a lot of us will assume that the patient knows nothing and then ask them a few questions and build on that. But the navigation does help because it sort of clarifies what patients are aware of beforehand.'* N6

There was a difference in how Navigation was used, and therefore accepted, by the neuro-oncology and colorectal clinicians. In the neuro-oncology clinic, consultations could end

abruptly following the news that a patient's tumour was incurable, due to the overwhelming nature of the patient's prognosis. The consultation plan helped neuro-oncology clinicians cover all the patient's concerns and questions before breaking such distressing news. In this way, neuro-oncology clinicians were enabled to tailor their delivery of information to ensure they would meet the patient's needs:

*'Also helpful from the doctor's point of view because we know the patient's understanding and what their questions are beforehand and particularly in the neuro-oncology clinic, I thought that was really good. That's where I first met Navigation and it's great because, you'd get patients coming in saying, the question would be: "I was told the blood clot was removed completely" and "do I need any follow up" and if you if you're sitting down and you're about to have a wee discussion with somebody about high grade incurable brain tumour and that's their level of understanding you know it's gonna be really tough and you know you're gonna have to take it slow.'* **N6**

Comparatively, the colorectal clinicians reported that receiving the consultation plan did not impact how they delivered information to patients, nor about how they told patients about treatment decisions:

*'I suppose it helped me in terms of what the focus of patients concerns are, but in terms of me giving the information it had no impact whatsoever.'* **C3**

*'I don't think that Navigation has changed the way that we talk to patients about treatment decisions.'* **C1**

All clinicians spoke about having a pre-existing consultation structure that was used to guide how they delivered information to patients in their consultation. This structure was to ensure all essential information was conveyed to the patient. The consultation plan was viewed by

colorectal clinicians as distracting from their usual structure of delivering information to patients. While neuro-oncology clinicians felt their usual structure used to deliver information often covered the majority of patients concerns listed:

*'If you use that as a way of delivering the information that you have to deliver about the plan, treatment course, you can become very detracted to things that actually might not be you know important in terms of the plan, okay they might be important to the patient.'* **C3**

*'Actually often the questions were about information we were going to give the patient anyway, so it was part of our, a big part of our consultation.'* **N7**

For one clinician, the consultation plan did not affect the order in which information was delivered, but it did appear to impact the emphasis and focus of information delivery to the patient:

*'It does kind of change how you think and how you phrase things and how much information you give to patients, you know, go through the history and the own format of what a consultation would be. But maybe focussing more on some of the areas the patient wants to talk about, and if there's anything major that we need to cover first of all then I would do that if there's anything major picked up.'* **N6**

In contrast, it was suggested by one colorectal clinician that the CP did not provide any further insight into a patient's questions or concerns as: *'We know what patients are concerned about.'* (**C1**). The clinicians identified that the consultation plan could become obsolete within the consultation. This occurred when a patient's expectation of their healthcare situation was different to the reality, and therefore the questions quickly became

irrelevant. In this instance, the consultation plan was useful in forewarning the clinician that the patient had little understanding of the news they were about to be informed of:

*'Often the questions that were less predictable were from the patients that we realised didn't really understand what was happening. And actually a lot of those questions become redundant when they did find out what was happening.'* N5

### *Impact on time*

All clinicians reported that the intervention had impacted on their clinic appointment schedule, requiring increased time commitment to read the consultation plan, ensure all questions were covered in the consultation, and later check the summary for accuracy. It was suggested, especially by the neuro-oncologists that although Navigation took extra time, this was worthwhile in enhancing the experience for the patient:

*'It certainly increases the, yeah even if it doesn't take that long to read the plan and check through the summary, it adds to the medical time, not dramatically but if we were doing it on large numbers of patients, it would add up.'* C4

*'I think everyone will say that it has taken a bit extra time and I think everyone will say it has been worthwhile.'* N7

To this end, neuro-oncology clinicians spent extra time searching for the information prior to the meeting, to ensure questions could be correctly answered:

*'It's not usually time consuming. You have to read through it, you sometimes, if there are any questions that the patient has that are going to be addressed, you may have to do a wee bit of reading around about that if it's not very clear in order to give the patient the correct advice.'* N7

Furthermore, the neuro-oncology clinicians reported that gathering and answering the patient's questions often took time within non-Navigated appointments. With the intervention, the patient had already spent time formulating their questions and were ready and prepared to discuss these:

*'...getting to understand what the patient questions are and that usually takes some time. Because if I were to ask them just as they came into clinic do you have any questions, they usually think oh I am under a wee bit of pressure here I haven't thought. Or I don't want to mention it right now, so the answer would be no. But if they have time to think about it or the family have some time to think about it, maybe get these questions down on the sheet of paper, and then they are more likely to get these questions answered.'* N7

An alternative view was held by the colorectal clinicians who viewed some of the questions on the consultation plan as inappropriate for their consultation. It was perceived that some questions added to the clinic appointment time and would be more appropriately addressed by the Clinical Nurse Specialist:

*'In a busy clinic its difficult, I guess, err, sometimes the plan put forward by the patient is completely different from what you would suggest are the important issues from the medical point of view, so it does lengthen the consultation sometimes.'* C2

*'There's a tendency sometimes for patients to eh focus on eh maybe topics that aren't necessarily the right topics for that particular circumstance ... yeah they're important issues but that's maybe not why we think they're coming to see us.'* C4

Topics deemed more appropriate for the clinical nurse specialist included the following:

*'The first few consultations patients were coming in and asking all sorts of things ... sometimes they were coming straight into medical consultations saying 'When can I go back to work?' 'What can I eat?' 'When can I go on holiday?'' C1*

However, when the clinical nurse specialist could spend time with the patient before their clinic appointment they used the plan and ensured these questions were addressed where possible:

*'Now a lot of the 'when can I go swimming?' is already dealt with and actually you can actually focus on core business.' C1*

A specific aspect of Navigation noted to be time-intensive was the checking of the summary for accuracy before it was sent to patients. This was seen as time consuming by clinicians who felt some of the content needed correcting thereby distracting from clinical time, although this was variably reported across the sample:

*'No I would always have a quick look through them just to make sure that it was an accurate reflection of what we had discussed um cos often our consultations are quite complex and it's important that the information is sort of accurately sort of, um, recorded.' N5*

*'It's not time consuming particularly. Takes a couple of minutes to read through.' C2*

### 9.4.3. Sustainability

This theme explores how relevant the medical staff perceived the intervention was for their service, and examines their opinions on whether the intervention in this form could be sustained in their practice and within the NHS.

#### *Applicability within the service*

It was clear that the intervention was seen as successful in helping patients understand what was important to them for their consultation:

*'I think the concept of patients having some sort of preparation and thought about the purpose of the consultation is reasonable. Quite how you put it into place is another matter. I think the navigation appears to work well as in the process of it works well'*

**C4**

However, concerns were raised regarding engagement of clinicians with the Navigation process. It was suggested that some colorectal clinicians were unfavourable of seeing Navigated patients (*'I think there's sometimes an element of 'you see that patient, they're navigating' C1*). All clinicians were asked if they would prefer their consultation with or without Navigation; two colorectal clinicians said without, two reported no preference and all three neuro-oncology clinicians reported they prefer their consultation with Navigation. A clinician with the experience of working in both specialities suggested reasons for this difference in acceptability and applicability may be due to a patient's care pathway, specifically how informed and supported a patient was by the health care team, prior to their first clinic appointment:

*'If we compare the bowel team to the brain team. so the bowel team they've got nurse specialists. So they'll see a surgeon, they'll get their diagnosis, they'll have their*

*operation, there'll be a nurse specialist who's been following them through, clarifying any points and, you know, making them aware of why they're coming to see us, and that group maybe benefit less than the, the brain tumour group where often it's a, it's a more hurried path with getting their diagnosis, their surgery, may or may not be told all of the information they need to know. A lot of surgeons in the hospital are still worried about saying the word cancer. Like you know, a patient coming to a cancer clinic without knowing they've got cancer is a big problem. ' N6*

This difference was supported by a neuro-oncology clinician who felt following surgery patients about to be diagnosed with a High Grade Glioma arrived at their appointment with very little awareness of the news they were about to receive:

*'I think for a lot of our patients as well, they have come via the neurosurgical route, and they don't often have a very good understanding of what's going to happen and so its maybe an opportunity for them to stop and have a think and come along a bit better prepared to the consultation. ' N5*

Colorectal clinicians reported very few treatment options were provided to their colorectal patients. As such they suggested clinical situations in which Navigation may be more useful. These health service areas broadly included; where more than one viable treatment choice is available, when there is a lot of information to convey and for those with multiple comorbidities.

*'With colorectal cancer for any given situation there's a fairly narrow lot of options and therefore it, I suspect Navigation probably doesn't have a huge impact on decision-making, It might have an impact on patient's understanding. ' C4*



*'I think it's potentially more important when there's diseases where there's a choice of two, three, four, five radically different treatments. Most of our Navigation is usually about a single decision of treat or not treat, which is, arguably a more straightforward decision that doesn't need a huge amount of navigating. So, I think there's some oncology settings it would be more useful, such as prostate cancer, where there's nothing... brachytherapy, radiotherapy, surgery and different forms of surgery, so a more complex decision.'* **C2**

It was further suggested by one clinician that the level of patient education and patient informed-ness may impact on the benefits gained by a patient from the intervention:

*'Very well educated, well informed patients maybe would benefit less from navigation because they tend to be the ones that have read up on things and tend to come in with questions and have very focussed aims from the consultation anyway. You know, maybe that's, maybe that's not true but um sort of eh, more average working class patients that may be: "I'll do what the doctor says and I'm not going to ask too much. I'm just", you know, "I'll do whatever I'm told to do". I think they maybe benefit more from navigation because they're encouraged to ask.'* **N6**

### *Feasibility within the NHS*

All clinicians felt the intervention in its current form was too resource intensive (time commitment) and therefore expensive, and would not be prioritised nor funded by the NHS:

*'It's difficult to see how it could be funded, staffed within the current limitations of the healthcare system financially.'* **C2**

*'On a day to day basis I am not sure how exportable it would be, I think patients would love it but I don't think the health service would pay for it.'* **N7**

One solution suggested was charity funding (*'I think this is something that charities would be interested in getting involved in.'* N7). An alternative solution was to integrate the role of the Navigator into the Clinical Nurse Specialist's role. Whilst these specialist nurses were perceived to hold the skills to undertake this i.e. specialist medical knowledge and developed communication skills, there were concerns that this could also be an expensive solution and that they may have little time available to integrate this into their role:

*'The navigators have got to be highly trained, have good medical knowledge, background. Good communication skills, that they can meet the patients, get on well with them, and help them understand what the problem is. As well as, help the doctor understand what the patient's issues are. Yeah, so they have got to be highly trained. Quite expensive I would probably say, not just someone off the street.'* N7

*'Too resource and time-intensive. Yeah eh I don't see it's realistic yeah I think there are certain aspects of the approach that could be maybe rolled into the job for clinical nurse specialists.'* C4

## **9.5. Summary of Findings**

This chapter has presented the views of the intervention from the consulting clinician perspective. All clinicians reported preparing for the consultation and being provided with a written summary was useful for patients. Within the intervention, patients were more likely to have all of their questions covered and were supported to recall the information provided. Furthermore, it was agreed Navigation was most useful at the initial treatment discussion.

Disparities in the acceptability of the intervention were present between the colorectal and neuro-oncology clinicians. Neuro-oncology clinicians appeared more favourable of the intervention. They used the consultation plan to inform them of a patient's understanding and

concerns in order to tailor their consultation to the specific needs of the patient. In contrast, colorectal clinicians felt the consultation plan negatively distracted from the focus of the consultation. All clinicians found the intervention added to their, already limited, clinical time. Neuro-oncology clinicians suggested this added time was added quality to the consultation.

When compared with colorectal participants, clinicians recognised the High Grade Glioma participants were less informed and received less health care support before their first appointment, due to their care pathway. This suggests HGG clinicians may have been more in need, and so more receptive of, the information and support provided by the intervention for their patients. This difference in care pathway and knowledge may help to explain some of the differences in clinician perspectives of the applicability of the intervention to their services.

All clinicians held the opinion the health service would not provide funding for this intervention. Charity funding was suggested. Clinicians believed Navigators should be highly trained in order for the role to work effectively.

The next chapter will discuss these findings in the context of the results from the RCT, findings from the participant's interviews, and relevant empirical literature.

## **Chapter 10: The Discussion**

### **10.1. Overview**

The aim of this study was to determine the effectiveness of Navigation in enhancing the quality of decision making in oncology consultations over time when compared to usual care. Furthermore, the study aimed to explore the experiences of the intervention from the perspective of the participants and their clinicians, when contrasted with usual care.

This chapter will begin with an overview of the study and a summary of the results. These will then be discussed in the context of current understanding and literature about the specific populations and the present evidence base of the intervention. This will be followed by focussed discussion on the applicability of Navigation in the context of oncology care and health policy. The chapter will conclude with a critical review of the methodological approach and limitations of this thesis.

### **10.2. Study overview**

To inform this evaluation, three studies were conducted in order to build evidence for use of the intervention over time and in the wider cancer population. Primarily, a longitudinal RCT was utilised with people diagnosed with colorectal cancer (CRC) to determine the effectiveness of the intervention from the point of post bowel surgery to the end of chemotherapy, compared to usual care patients. Secondly, qualitative evaluation was undertaken with CRC trial participants to contrast the experiences of the intervention with usual care. In addition, evaluation of the intervention with a cohort of people diagnosed with High Grade Glioma (HGG) was utilised to enable comparisons of experiences with the intervention across specialities. Thirdly, qualitative evaluation was undertaken with HGG and

CRC consulting clinicians to further the understanding of the intervention's relevance and utility from the service provider perspective.

### **10.3. Summary of results**

Information sharing and decision making during oncology consultations is complex. All participants acknowledged the need to plan for their involvement in consultations and engage in decision making about their cancer treatment. In reality, achieving this as part of usual practice was challenging.

Use of Navigation with CRC participants did not improve decision self-efficacy ( $p < 0.05$ ) nor reduce decision conflict ( $p < 0.05$ ) throughout the course of treatment for their cancer. All participants felt participation in decision making was limited to accepting or declining the treatment recommendation. However, the consultation planning stage of the intervention did significantly increase intervention participants decision self-efficacy ( $p = 0.04$ ) in preparation for their initial clinic consultation. Navigation also significantly prepared intervention participants for decision making ( $p > 0.001$ ) in the consultation. Intervention participants reported that consultation planning prepared them for their consultation, as the Navigator enabled them to critically reflect on their information needs and formulate their questions. Within the consultation, use of the consultation plan ensured participants information needs were satisfied and provided consulting clinicians with an awareness of their patient's understanding. Summaries provided intervention participants with a reassuring safety check for recall of information throughout their treatment, whereas usual care participants felt they were missing important and informative pieces of information. At follow-up, once a participant had experienced the consequences of the treatment decisions, intervention participants reported significantly less regret than usual care participants ( $p = 0.039$ ). Engaging

with the intervention did not impact anxiety or depression scores as measured at follow-up ( $p>0.05$ ).

Navigation was variably received by clinicians. HGG clinicians were supported to deliver best practice by the intervention, while in contrast CRC clinicians found the intervention disruptive and time intensive. Despite the benefits identified by participants receiving Navigation, concern was expressed by all clinicians regarding the resourcing and sustainability of Navigation in the NHS.

To give more depth to the summary, the primary focus of this thesis was whether use of the Navigation intervention improved decision self-efficacy (DSE) in CRC and HRG patients. This was not demonstrated: Navigation did not impact on DSE, over time ( $p=0.74$ ,  $p=0.91$ ,  $p=0.96$ ). Overall, DSE scores were high at baseline and during the course of treatment for control and intervention groups. Similarly, Navigation did not impact on the secondary measure of decision conflict (DCS), measuring uncertainty in decisions, over time ( $p=0.08$ ,  $p=0.57$ ,  $p=0.58$ ). All participants reported low DCS, and this was maintained over time from baseline to follow up. However, at the mid treatment appointment, Navigation participants did report lower uncertainty than control participants ( $p=0.001$ ).

The lack of impact of Navigation on decision making may be understood in the context of the perception of limited CRC and HGG treatment options that participants could influence.

Clinicians, particularly CRC clinicians, reported cancer treatment decisions were limited given that cancer treatment pathways were well mapped out. Participants perceived decisions about treatments to be reduced to accepting clinician's recommendation, or not. Given the nature of HGG and CRC and prognosis, patients did not see this as a decision they wished to

take responsibility for. Participants accepted clinicians as the experts in their care, best placed to make the treatment decisions. This could explain the high level of confidence in decisions, low level of uncertainty in all participants, and lack of impact of Navigation on primary and secondary outcomes.

All participants recognised the benefits of pre-planning for medical consultation. However, participants experiencing usual care found it challenging to allocate time to plan and despite using some resources e.g. the internet to prepare, a significant number of barriers to information exchange in medical consultation were identified. These included: forgetting questions; lack of dedicated question time within consultation; difficulty of asking questions with new clinicians and a tendency to assume a passive patient role with clinicians. In contrast, Navigation enabled patients to plan, be prepared for their consultation and identify areas of information need. This is supported by limited RCT data and more extensively by qualitative findings. CRC intervention participants were more prepared for decision making when compared to control participants after all three consultations, as evidenced in the four item Preparation for Decision Making scale ( $p > 0.001$ ). Consultation planning supported intervention participants to critically reflect on their information needs for the medical consultation and significantly increased decision self-efficacy within the intervention group. Specifically, consultation planning enabled participants to articulate and formulate their questions, prioritise and focus key concerns and consider questions for discussion beyond medical results and management. For HGG participants, consultation planning facilitated difficult conversations between partners resulting in a shared agenda for their consultation. The consultation plan provided a template for use in the consultation to ensure all questions were attended to. Furthermore, the consultation planning gave patients the confidence to ask

questions, helped them to manage anxieties and provided reassurance that clinicians had prepared for their discussion.

Provision of the Navigation summary was helpful to participants, with preference given to the written, as opposed to the audio, summary. Clinicians were supportive of the summary, although the lack of resources available to produce this were noted as a limitation. The frequent checking of summaries by participants, thereby providing reassurance and information when needed, may explain why scores of decision conflict were significantly lower for intervention participants at their mid-treatment appointment.

The concern from CRC Consultants that Navigation may increase patient anxiety, was not supported by RCT results where mood, as measured by the HADs, was not impacted by the intervention (HADS-A  $p=0.54$  & HADS-D  $p=0.56$ ). Levels of anxiety and depression were low for all participants and decreased at follow up. However, the percentage of participants reaching the threshold for anxiety increased at follow up for the control group (12.5% at baseline, 20.59% at follow up) and decreased for the intervention group (25% at baseline, 20.51% at follow up).

Navigation significantly reduced the regret experienced by participants about their cancer treatment decisions ( $p=0.039$ ). CRC intervention participants reported significantly less regret than their control counterparts at follow up ( $p=0.039$ ). Participants who received the intervention (HGG and CRC) appeared more aware and knowledgeable about their treatment, demonstrating realistic expectations of treatment side effects and symptoms. The consultation summary was particularly useful in this regard. This was in contrast to control participants who talked of the unknown and reported learning of treatment side effects



through trial and error. Furthermore, for control participants, the amount of appointments attended was related to an increased decision regret score ( $p=0.038$ ). It could be conjectured that more appointments related to a more complex situation in which understanding one's situation becomes ever more crucial.

Clinicians held mixed views on Navigation and its use in medical consultation. HGG consultants perceived Navigation as preparing patients for taking part in the medical consultation and as a tool to help medical staff understand patient's information needs. HGG clinicians used the consultation plan to inform content and delivery of information. In contrast, for CRC clinicians, the consultation plan was a helpful checklist to ensure all questions were covered at the end of the consultation but it did not impact on the way that information was delivered or how decisions were framed.

Clinicians were concerned about the applicability and sustainability of Navigation within health care. CRC clinicians reported Navigation to be time intensive and not relevant to CRC practice, although possible preference sensitive pathways were suggested. In contrast, HGG clinicians identified Navigation as supporting cancer consultations, thereby supporting them in providing a higher quality service for their patients. All clinicians expressed concern as to whether Navigation would be financially supported by the NHS.

Four areas are now considered for discussion to further understand the effectiveness of the intervention within the two populations and within this health care setting: Navigation and the cancer populations CRC and HGG; Navigation for people with cancer; and the applicability of Navigation within the NHS.

## **10.4. Navigation and cancer populations**

This section will examine results of this thesis in the context of what is currently known about Navigation in CRC patients and HGG patients and what this study adds to the body of knowledge in this area. The section will conclude by comparing and contrasting this study's results with the body of evidence already attained about the Navigation intervention.

### **10.4.1. Navigation in a population of people with colorectal cancer**

This study aimed to establish effectiveness of Navigation in enhancing decision quality within a colorectal population during first line treatment with chemotherapy. There is a body of evidence, explored earlier in this thesis that outlines the uncertainty and concern experienced by cancer patients at diagnosis and during cancer treatment (Wilson et al., 1999), and the negative impact that this can have on the patient's experience of cancer (Shaha, Cox, Talman & Kelly 2008). With information seeking behaviours proposed as strategies to minimise distress (Shaha et al., 2008) at critical time points throughout the CRC trajectory (Knowles et al., 1999), the potential impact for interventions such as Navigation are clear. However to date, studies exploring information needs and decision-making preferences within the CRC population have provided a paradoxical description of both patient passivity and patient engagement.

In this evaluation thesis, there was strong evidence of CRC participants' delegating treatment decision making to their clinicians. The rationale provided by CRC participants for this action are in line with the CRC specific literature and the general cancer population literature. The nature of decision making and patient choices in colorectal cancer care have been well explored in a series of studies by Beaver et al. (2005, 2007, 2009) where focus of these UK studies were on information and decision making preferences of CRC patients and their

clinicians. These studies are useful in providing contrast and comparison to the findings of this thesis.

CRC participants in the qualitative evaluation of Navigation described a strikingly similar account of decision making in their healthcare consultation when compared to CRC participants interviewed by Beaver et al. (2005). CRC participants interviewed by Beaver et al. (2005) perceived that they were informed and advised about treatment options, rather than provided with choices. Although such treatment recommendations were provided, participants perceived there was a 'right' choice and they were fearful that they may chose erroneously (anticipated regret). The fear of making an incorrect choice was based on patients not having knowledge about the treatment options and having difficulty with fully understanding the complex medical language (Beaver et al., 2005). Consequently, participants delegated decision making to doctors who they perceived as the experts in their care and therefore the professionals who would provide the most beneficial treatment (Beaver et al., 2005). In a further study where CRC patients (n=375) were surveyed about their attitudes towards decision making, 95.2% (n= 357) of participants trusted their clinician to decide and 84.8% (n=318) reported clinicians had the medical knowledge and so should decide what treatment was best (Beaver et al., 2009). In addition, through administering a survey that explored decision making with colorectal cancer participants, it was found trust in the clinician was integral for CRC patients in accepting decisions (Salkeld et al., 2003). In this thesis, CRC participants were confident that their clinician would make a treatment recommendation based in their best interests, which for participants was to extend their life for as long as possible. In conjunction with findings from the Beaver et al. (2005 & 2009) studies, the findings from this thesis suggests that either how decisions are made during the CRC care and/or how the CRC patients perceive their role decision making has been

relatively unaffected by the more recent policy drivers that have strongly steered a course towards a shared decision-making approach (NICE 2011, DH, 2011a, SIGN 2015).

CRC participants and their clinicians in this Navigation evaluation reported there was minimal patient involvement in the treatment decisions, with any involvement limited to accepting or declining treatment. Beaver et al., (2007) similarly found through interviews with health care professionals that treatment choices were limited for CRC patients as complex management plans were created during separate multi-disciplinary team meetings devoid of patient input. Such management plans were then presented as recommendations to CRC patients during their clinic appointments. Similar findings with regards to lack of CRC patient involvement in treatment decisions were identified in a study undertaken by Nagler et al. (2010) who hypothesised that this was due to the lack of treatment options inherent in following a standard treatment pathway of care. This raises the question whether there is need for Navigation within clinical situations where a defined pathway of care exists. As proposed by CRC clinicians in this thesis, if the aim of Navigation is to encourage shared decision making, findings from this work question whether certain cancers and even disease trajectories may be more suitable to Navigation than others. This will be revisited and further discussed later in this chapter.

Whilst a key finding from this thesis was that neither Navigated nor usual care participants felt able to impact on the outcome of the treatment decision, it was clear that patient participants wanted to be involved in the process of decision making, without holding responsibility for the final outcome. Similarly Beaver et al. (2009) found 94.7% of patients wanted to know what was happening and be involved in decisions, but only 51.7% wanted to make the final decision. Clinicians in Beaver et al's (2007) study reported that their patients

wanted to be guided in decisions. This position of patient engagement was similarly held by the CRC participants in the qualitative study. Participants ultimately wanted to be guided to understand the decision, not challenge it. This distinction between involvement in the process of decision making and not the outcome of decision making, so clearly articulated in the qualitative evaluation in this thesis, was key to understanding what was important for CRC participants in this thesis.

The qualitative findings have clearly defined involvement in the decision making process as a key aim for participants. What is less clear is why this did not impact on primary and secondary outcome measures. There is evidence that cancer patients who experience strong treatment recommendations during consultation, subsequently report significantly less involvement than those who do not perceive strong recommendations to be made (Frongillo, Feibelman, Belkora, Lee & Sepucha, 2013). However, what is interesting is the perceived level of involvement did not impact on the participants rating on the Decision Conflict Scale. No significant differences were found on the reporting of the DCS between participants who reported feeling involved compared to those who did not. This finding suggests that the DCS measure may not be sensitive to the changes affected by the Navigation intervention given that qualitative patient reports demonstrated improved involvement in the consultation. However, it also raises whether involvement in the process of decision making constitutes as shared decision making (SDM) thereby revisiting the question posed earlier: whether SDM speaks to decision-making processes or decision-making outcomes.

When patients delegate making decisions about clinical treatments to clinicians, patients are often described as taking a passive role in their care (Tariman, Berry, Cochrane, Doorenbos, & Schepp, 2010). To identify CRC participants as ‘passive’ simplifies the reality of the

clinical situation. All participants in this study actively engaged in behaviours to gain some understanding of their situation, but with acceptance that clinicians would make the final decision. The amount and type of information provided to patients and the environment created by their clinicians had a direct impact on how involved patients could be in decision making. However, clearly there was tension for patients about the level of involvement in decision making and if this would impact on the decision outcome.

When reflecting on the nature of SDM in this thesis, the question posed by Clayman and Makoul (2009) comes to mind: is SDM engaging in the final decision or is SDM engagement and sharing of the decision making processes? An early exploration of this area indicated that a lack of involvement in decision making where the decision outcome cannot be influenced is not and cannot be seen as a ‘shared’ decision (Charles, Gafni, & Whelan, 1997). This may be perceived as a rigid view on SDM, although decisions about CRC treatment were ‘set’, CRC participants perceive that decisions would only be made with their consent and acknowledged that they had the option to decline treatment, which some of them did indeed chose. In this way, it could be seen that participants could indeed influence the outcome, although in a limited way.

The decision-making behaviours described by CRC participants in this evaluation and Beaver et al.’s work (2005, 2009) demands a revisiting of the conceptualisation of SDM to clarify the definition of patient participation in SDM with regards to decision-making processes and outcomes. This will help to clarify the relevance of SDM in circumstances where treatment decisions are heavily guided by clinical evidence.

Patient engagement in the decision-making process in this evaluation, was enabled by the participation in clinic consultations through asking of questions and gaining information. Whilst traditionally, these are areas of difficulty for patients (Beaver et al., 2005), Navigation enabled participants to gain information about their disease and its treatment, thereby building knowledge and aiding understanding, rather than informing decision making; this is an important and nuanced finding of this work. Consultation planning was especially important in achieving these outcomes. Within qualitative accounts, intervention participants expressed confidence in asking their questions whilst control participants reported difficulties in finding space and time in the consultation to ask their questions.

Consultation planning gave a structure to achieve effective communication within the consultation appointment, with Navigation summaries used after consultation to ensure understanding of the information shared during the clinic. Time is well recognised as a barrier to information sharing in consultations (Frosch, et al., 2012), as is the challenge for patients when communicating complex information (Joseph-Williams Natalie, Edwards & Elwyn, 2014). For participants experiencing usual care, and as reported previously by Beaver et al. (2010), learning was more a process of trial and error in seeking information.

Assimilating information in this way during usual care holds a risk of having misleading expectations about treatment. Indeed, this may have impacted upon the CRC control group's scores of regret. However, it remains unclear as to why Navigated participants scored significantly lower regret when, for the majority of participants, regardless of trial arm, the fear of choosing incorrectly was the driver for delegating the decision to the clinician.

As discussed in Chapter 2, it is well understood that receiving a cancer diagnosis and undergoing chemotherapy treatment for CRC provokes anxiety, specifically regarding

chemotherapy side effects and the possibility of needing to discontinue treatment (Beusterien, Tsay, Gholizadeh & Su, 2013). However, the prevalence of anxiety and depression in this evaluation study was not impacted on by the Navigation intervention. There may be some understanding as to why this may be so. A systematic review determining whether anxiety was an appropriate measure of decision aid effectiveness concluded against its use (Bekker, Legare, Stacey, O'Conner & Lemyre, 2003). The authors advised that increased anxiety levels may actually be beneficial to the decision making process resulting in better recall and systematic evaluation of information. However, this thesis does not support that conclusion: the mean change in anxiety reduction was more for intervention (-0.95) than control (-0.42) participants pre-post with whole group mean scores of anxiety and depression declining from baseline to follow up.

A relatively large proportion of this study's participants were identified as experiencing high anxiety ( $\geq 8$ ) at baseline 36.72% and follow up 32.43%, compared with 19% ( $n=24$ ) of a total CRC sample ( $n=128$ ) tested by Simon et al., (2009). However high depression prevalence ( $\geq 8$ ) appeared relative (20.31% at baseline and 13.51% at follow up) when compared with a meta-analysis ( $n=211$ ) of depression prevalence in the general population of cancer patients, which found 17% (95%  $CI=16-19\%$ ) of participants were highly depressed (Krebber, et al., 2013). Patel et al., (2011) found 9.64% of CRC participants met the criteria for a depressive disorder ( $\geq 10$ ) and 6.14% met the criteria for anxiety ( $\geq 10$ ), 9 weeks post diagnosis. Comparatively more of this study's population were clinically anxious (18.75%) but less were clinically depressed (4.05%). These comparisons could infer the sample studied included a higher prevalence of people experiencing high and clinical anxiety.



This study has provided further support for the evidence that colorectal cancer patients want to be involved in the process of decision making to understand their situation and the impact of treatment, but not the outcome. It is unclear if this is an attitude unique to the experience of colorectal cancer. It is also unclear if this attitude is an antecedent to or a consequence of CRC clinician's presentation of treatment decisions. Navigation was able to help CRC participants overcome the barriers to getting involved in the process of decision making to support and facilitate the two way communication between the clinician and patient. Although shared decision making was not achieved, as indicated by the measures, the qualitative report suggest the intervention did support the attainment of individualised information to satisfy needs and reassure participants throughout their treatment.

#### **10.4.2. Navigation in a population of people with High Grade Glioma**

This thesis has qualitatively evaluated an intervention which aimed to support HGG participants' involvement in their cancer care and treatment choices. This has been an area identified as needing review for some time, as demonstrated in the results of two substantial literature reviews on HGG patients' information needs (Davies & Higginson, 2003; Catt et al., 2008).

Chapter 2 has already detailed the nature of the HGG disease with more common pathway of care beginning with rapid initiation of urgent hospital treatment (Guilfoyle et al., 2011). This results in the person receiving the diagnosis of HGG following surgery, often with little awareness as to the impact of the information that will be shared with them during the following medical consultation; indeed this perspective was confirmed by the HGG clinicians in this evaluation. With current HGG life expectancy reported at 12 to 14 months (Stupp et

al., 2005), it can be appreciated that the information shared during that initial medical consultation is literally life changing for patients, and therefore often traumatic.

Navigation participants, similar to the experiences of HGG patients in other studies (Leopola et al., 2001; Keir et al 2008), experienced profound distress and shock in adjusting to a HGG diagnosis. The impact of this diagnosis, and of the uncertain future that lay ahead, was also experienced by their next of kin/carers and their wider social support network as evidenced by direct report from partners within interviews. This finding on the impact beyond the patient/carer dyad supports previous findings from Sterckx et al. (2012). In acknowledging the devastation caused by receiving the diagnosis of HGG, the impact of Navigation on HGG patient decision making and on the decisions made, is now considered.

HGG participants, all of whom received the Navigation intervention in this thesis, did not perceive opportunity to take responsibility for decisions made about their treatment. In this way Navigation did not succeed at involving HGG participants (nor in fact CRC participants) in the outcome of their treatment decisions. When triangulated with interview data from HGG clinicians, it appeared this was due to clear clinical guidance and pre-determined treatment pathways that directed clinical treatments for a high grade glioma. For HGG patients to accept medical treatments, meant that there was some hope for the future, whereby to refuse treatment would result in certain and early death for the patient. Participants perceived clinicians as working to include them in the process of decision making and making decisions based on their best interests. However, participants also acknowledged that with no viable alternatives provided, the reality of this meant that their involvement in the decision making was, in fact, minimal. This corroborates findings by Halkett et al., (2009) who identified that it was difficult for patients to be actively involved in treatment decisions when the treatment

was effectively reduced to treat or not treat. This situation is particularly pertinent for HGG patients where no alternative treatment options are realistically available. Although the literature suggests that with time, patients wish to have greater involvement in treatment decision making (Shaha et al., 2008), the reality of this is difficult when treatment decisions are perceived in such a binary way.

There are two important points to come from this finding. Firstly, Navigation did not impact on the outcome of a patient's decision making due to a lack of treatment decisions in a disease with well-established and evidence based treatment pathways. This again raises the issue of the place of decision support tools, such as Navigation, in clearly defined pathways of care. Secondly, that the initial consultation, where the diagnosis and treatment decisions following surgery were initially shared between clinician and patient, was extremely influential for patients. Although the focus of HGG interviews was to reflect back on experiences over a minimum of three consultations, as seen in the data excerpts all participants focused their accounts on experiences of decision making during the initial medical consultation. Given the significance placed by patients on this time, this indicates the fundamental importance of this consultation, in how it is conducted, and in the decision making process used in influencing patient's healthcare experiences.

Although involvement in the outcome of decisions was not successfully achieved for Navigated patients, the patient's qualitative experiences of involvement in the decision making process, including information gathering, sharing and recall, were improved when compared with other studies. Participants in this Navigation study reported information needs were satisfied, and recall of information was supported. These experiences contrast with many studies that explore the usual care experience for people diagnosed with a HGG. This

usual care experience is often defined by a lack of, and need for, clinical information about treatment (Strang & Stang, 2001; Janda et al., 2006; Halkett et al., 2009; Cavers et al., 2012), resulting in patients feeling ‘left in the dark’ about their situation (Cavers et al., 2012, p.1301). Having appropriate information has been found to reduce anxiety for many people with HGG (Cavers et al., 2012) and whilst Navigation was not able to take away the uncertainty inherent in a diagnosis of HGG, it did appear to allow patients to feel reassured that they understood their situation and were informed about the challenges they were facing.

It is clear that many HGG patients leave medical consultations wishing that they had asked more questions and wanting more information about their prognosis during the course of the treatment, and indeed beyond (Diaz et al., 2009). In addressing such concerns, the opportunity and space to ask clinicians’ questions is known to be a useful strategy in managing the uncertainty and furthering understanding of a HGG diagnosis and the treatment decisions (Halkett et al., 2009). Through the consultation planning stage of the intervention, participants were supported to critically reflect on their situation to generate important questions and information to share with their clinicians. Participants acknowledged this to be a beneficial aspect of Navigation enabling them to ensure that the consultation was planned so that they would receive the clinical information they needed. Through clinician use of the consultation plan participants perceived the information they received as high quality and tailored to their specific needs, this left them feeling known and attended to as an individual. Tailored information is known to be an important aspect of care for HGG patients (Halkett et al., 2009) and is also reported in qualitative data gathered about consultation from a general cancer population (Thorne et al., 2005). In this study the authors defined ‘being known’ as an acknowledgement of the individual as a unique person, distinct from the disease (Thorne et al., 2005). These findings support Bensing and Verhaak’s (2004) theory of need in the

medical consultation which reports patients have both a cognitive need, the need to know and understand, and an affective need, the need to feel known and understood.

Whilst the consultation planning stage of Navigation clearly had benefit for the participant, data from HGG interviews also addresses some of the social awareness concerns to arise from Salander & Spetz's study (2002) on how patients and partners discuss HGG together. The way in which consultation planning brought patients and their partners together to ensure a shared agenda of questions before the consultation was another unique finding of this thesis. Cavers et al., (2012) noted that differences in information preferences between relatives and patients was often a source of tension and distress. This is reported to be a complex area with carers noted to have a higher need for information than patients (Salander & Spetz 2002) and yet also patient satisfaction of information received reported as being greater than that of their spouse (Catt et al., 2008). Such discrepancies between patient and partner need were not revealed in this Navigation work with patients and their partners felt supported to plan for the appointment together and discuss their information needs. Although coping strategies such as denial and distraction activities are reported during information seeking and discussion about HGG (Cavers et al., 2012), HGG consultation planning undertaken by an independent trained Navigator appeared to facilitate, enable and encourage open and direct discussion between parties.

The consultation planning phase of Navigation involves two components: development of a prompt list of questions; and coaching from a Navigator. It is clear that HGG participants felt supported by the presence of their Navigator throughout their clinic appointments. This is not surprising given that in a review of the literature, Catt et al. (2008) identified HGG patients as wanting someone to listen to their views about care. In turning attention to the prompt list, a

recent study exploring use of the Patient Concerns Inventory (PCI), a list of prompt items to discuss within the consultation, found use of the PCI provided focus for consultation and facilitated the asking of questions, requests for further referrals and support in care (Rooney et al., 2014). However, when interventions such as question prompt sheets or decision aids are combined with coaching, as in this Navigation intervention, this can further improve knowledge and the satisfaction of information needs (Stacey et al., 2012); although review of the literature offer conflicting results here (Stacey et al., 2013). It is difficult to identify which component of the Navigation had most impact here (prompt sheet vs. Navigator). What is clear from the qualitative evaluation of Navigation is that participants valued the ‘human element’ of the intervention, finding that the consultation planning assisted them in clarifying their thoughts and questions prior to consultation. It also encouraged question asking within the consultation.

HGG participants in this study reported that having a record of the consultation was helpful in aiding recall of information. Similar to findings in Halkett et al.’s work (2009), both verbal and written information was helpful in remembering what was discussed with them during initial consultations because at the time they were numb with shock and unable to absorb the information given (Cavers et al., 2012). A particular finding about the Navigation summary in HGG patients, was how it was used to pace the uptake of information by the patient according to their individual adjustment to the diagnosis. This approach of staging uptake of information through assimilating incremental doses of information has been reported as preferable for HGG patients as they gradually come to terms with the reality of their disease and prognosis (Rosenblaum et al., 2009). With the Navigation summary, participants were provided with a factual account of their situation and, as discussed before, this appeared to reassure rather than instil anxiety in HGG participants. Summaries were also used to provide

detailed and accurate information to loved ones who could not attend the consultation. This was particularly valued by HGG participants as Navigation summaries were used to support conversations with others about HGG and reassure loved ones with accurate up to date information. This is an important finding as often talking about HGG, its treatment and prognosis is an area that can lead to miscommunication and unrealistic expectations in others (Moore et al., 2013).

Findings from this study have identified that all components of the Navigation intervention were important in order for participants and their partners to have their information needs met. This is important given that when compared to other cancer populations, HGG patients find clinical information and advice hard to access (Adelbratt & Strang 2000; Davies, 2011). This study is the first to provide understanding of how the unique combination of elements within Navigation can enable and support patients and clinicians to share information and meet patient information needs in a HGG population. Although small scale and qualitative in nature, this study has provided evidence to indicate further study of Navigation with HGG participants is required. Furthermore, comparable interventions such as the PCI, which may be a more cost effective intervention, also require further study to contrast strengths and weaknesses between the interventions.

### **10.5. Navigation for people with cancer**

This work has extended the body of evidence for Navigation by exploring its effectiveness as a decision support and communication aid for patients with CRC and HGG. As reported in Chapter 3, the Navigation intervention was originally designed by Belkora (2005) to support breast cancer patients in their decisions about medical treatments. This complex intervention, with its key elements of question prompt sheet, coaching and provision of a summary and

recording, has now been trialled in America with breast cancer patients (Belkora et al. 2008, 2015) and more recently in Scotland with prostate cancer patients (Hacking et al. 2013, 2014). In using Navigation with CRC and HGG patients, this further extends this body of work into new cancer populations.

In addition, this is the first work to undertake a longitudinal mixed methods exploration of Navigation, thereby building understanding of how this intervention works across a primary cancer treatment pathway. This section will now compare and contrast outcomes of the different Navigation studies to understand what knowledge has been added by this study about the impact of Navigation across different cancer populations.

To provide structure to this discussion on how this thesis, undertaken with CRC and HGG cohorts situates, compares and contrasts with other studies in other cancer populations, the first area to be discussed focuses on the primary and secondary outcome measures.

Within this thesis, no significant difference was found in the primary (DSE) and secondary outcome (DCS) measures between groups across each consultation. This contrasts with results obtained by Hacking et al. (2013), in a RCT study that tested the feasibility, acceptability and effectiveness of Navigation in early state prostate cancer patients ( $n=50$  intervention, 40 control). Hacking et al. (2013) found a significant change in DSE score between control and intervention groups following the initial consultation ( $p=0.01$ ) and this was maintained at six months follow up ( $p=0.03$ ). This thesis did not measure decision self-efficacy at follow-up due to concern that the time from the decision making to follow-up would lessen the validity of this scale (O'Connor, 1993).



In the baseline DSE scores reported by Hacking et al. (2013) Intervention DSE baseline scores ( $M84.9$ ,  $SD13.3$ ; Control  $M81.9$ ,  $SD17.1$ ) were comparable to this study's Intervention DSE baseline scores ( $M84.24$ ,  $SD1.86$ ; Control  $M79.83$ ,  $SD1.83$ ). Participants in this thesis and the Hacking et al. (2013) sample had a relatively high baseline level of decision self-efficacy. These results are also similar to those reported by Belkora et al. (2008), although in Belkora's study the DSE scale was scored using a range of 1-5. The challenge of such a high baseline score is that it limits the amount of improvement that can be detected following exposure to an intervention. Although this measure has previously been shown to have a large effect size (0.85) when evaluating the intervention (Belkora et al., 2008) it was not impacted by the intervention within this current evaluation population. Interestingly, in contrast Hacking et al. (2013) found a significant difference between groups (intervention vs. control) post initial consultation ( $p=0.011$ ), intervention participants reported higher decision self-efficacy when compared with usual care with this difference maintained at six month follow up ( $p=0.032$ ). This difference in results may highlight the differences in the patient populations being studied. Within the Hacking et al. study (2013) the population was patients diagnosed with prostate cancer. This is a disease with preference sensitive decisions that require the patient to decide their own treatment as clinical evidence is balanced in favour of more than one alternative (Hacking et al., 2013). In contrast, the CRC pathway has a clearly defined and evidence-based treatment plan which requires little input from the patient, or deliberation with the clinician.

However, there were further differences in the outcome measure of DSE from this evaluation study and with previous work. With regards to patient reports of DSE measured for intervention patients only from baseline to post-consultation planning (pre-consultation) Hacking et al. (2013) found no impact of consultation planning on participant reports of DSE

( $p=0.053$ ). In contrast the RCT in this thesis identified that consultation planning did significantly increase participant's report of decision self-efficacy ( $p=0.044$ ). Belkora et al.'s work (2008, 2015) also found the DSE scores increased post consultation planning ( $p<0.001$ ). This study therefore adds to this body of knowledge by suggesting that Navigation consultation planning increases decision self-efficacy, although it cannot offer any results to support that Navigation increases DSE when measured post consultation. As a RCT that administered serial outcome measures, this study provides new evidence that multiple exposures to Navigation over time does not appear to impact on scores of DSE in the CRC population, however it must be acknowledged that this study was underpowered over time.

Within this evaluation study, decision conflict was also not impacted by the Navigation intervention over time. In contrast, Hacking et al. (2013) found scores of DCS were significantly different post consultation ( $p=0.047$ ) although this was not maintained at follow up ( $p=0.052$ ). When comparing, in this study, between group scores at each time point (post consultation mid treatment, end of treatment and follow up) scores were found to be significantly different at the mid treatment appointment ( $p=0.007$ ) in favour of the intervention participants. In this way, this thesis can provide evidence that repeated exposure to Navigation may impact on DCS, however this was not maintained over time. Furthermore interaction effects could suggest this may not be due to the intervention.

Whilst such contradictory and conflicting evidence may prove perplexing, there were some outcome measures that demonstrated similarity with previously published Navigation work. The HADS was not impacted by the intervention in this study or in Hacking et al.'s work (2013). Additionally, scores of decision regret were significantly different between groups at follow-up in this study ( $p=0.039$ ) and in the Hacking et al. (2013) study, also taken at follow

up ( $p=0.036$ ). This study therefore provides further evidence to support that Navigation significantly reduces decision regret when measured six to nine months after the initial treatment consultation. It further supports that repeated exposure to Navigation does not impact on this significant finding.

Participants in this thesis were significantly more prepared for decision making than control participants after each consultation ( $p>0.001$ ) although due to the framing of the questions, these may have been biased in favour of the intervention group. Belkora et al. (2015) and Hacking et al. (2013) both used the same items from the Preparation for Decision Making scale but only used these with intervention participants, and not the controls. In making accurate comparisons across the studies there are some further challenges. Hacking et al. (2013) only provided percentages of responses to the items, thereby limiting comparison. However, Belkora et al. (2015) used three items from the preparing for decision-making scale and reported the mean score for each item: think how about involved you want to be in decisions ( $M4.17$ ); identify the questions you want to ask your doctor ( $M4.02$ ); prepare you to talk to your doctor about what matters most ( $M4.25$ ). This thesis found very similar results at post consultation (T3) respectively reported;  $M4.50$ ,  $M4.67$ ,  $M4.69$ . It can therefore be concluded that this thesis provides evidence that, due to high mean scores being maintained after each consultation, Navigation prepares participants for decision making for consultations throughout the first treatment pathway.

Earlier chapters in this thesis have detailed how cancer care patients find it difficult to understand and articulate their treatment preferences and to explore concerns about prognosis and survival in medical consultations where medical staff are often perceived to be too busy, afraid or unskilled to talk about such matters (Adelbratt & Strang 2000; Strang & Strang

2001). With cancer patients clearly recognising that health care professionals need to be aware of their information needs and to tailor the way information is provided (Halkett 2010), the thesis adds to understanding of the importance of two-way communication for both CRC and HGG patients.

Qualitative evaluation in this thesis demonstrated that Navigation improved communication between clinician and patient from the perspective of the patient. Although patient participants reported not being involved in the outcome of treatment decisions, intervention participants strongly reported feeling involved in the decision making process. What was striking throughout the analysis was the similarity in experiences of Navigation between the two oncology populations (HGG and CRC). Many studies examine information needs and patient experiences across oncology populations and it can be difficult to ascertain whether findings are resultant from the impact that the cancer and the cancer journey has on patient experiences, or are resultant from other factors e.g. impact of experiences at that cancer clinic or setting. There is no current consensus on this in empirical work. Beaver et al. (2005) have drawn comparisons between the experience of breast and colorectal cancer and found differences in decision making preferences. By comparing the qualitative reporting of experience of Navigation from the perspective of someone with breast cancer (Belkora et al. 2009) to this study with colorectal cancer it can be argued the reported experiences are comparable. Given that qualitative findings from prostate cancer patients in Hacking et al.'s work (2014) are comparable with findings of Navigated CRC and HGG patients in this thesis, it would appear that the cancer site does not impact on the experience of Navigation when reported qualitatively; however quantitative differences, as discussed earlier in this discussion, are present. This raises the question about whether the quantitative measures used within this evaluation are sensitive to or valid to measure patient outcomes of the encounter

with Navigation. Further work to evaluate Navigation with different measures is recommended, particularly when there are no preference sensitive decisions.

As a decision and communication support intervention, Navigation offers support through several mechanisms including: consultation planning, coaching and provision of a consultation record. All intervention participants in this thesis found the consultation planning to be most helpful. This supports Belkora et al. (2009) who reported the experience of Navigation through case study with a breast cancer patient. In this, the participant reported consultation planning to be beneficial in helping her to clarify and think through questions. The participant reported finding value in knowing that the clinician could set the delivery of information to her individual level of understanding. This resulted in a discussion weighted less on the discovery about what was important to her and more on what she wanted to discuss. Similar to patient experiences reported in Chapter 8, the participant in Belkora et al.'s case study (2009) reported clear understanding and recall of information shared during the consultation, noting the difficulty of remembering the small issues discussed whilst attempting to process the bigger picture of the situation of her diagnosis.

Another significant finding from this evaluation thesis is the importance of each component of Navigation for patients. A key issue for Navigated patients in this work was how the consultation planning helped them prepare for the medical consultation. This has also been identified by Hacking et al. (2014) where such planning also prepared patients to take part in the consultation by asking questions of their clinician. Following the consultation, across all Navigation studies, the written summary and CD were used to recall and further understand decisions made. A key component of this complex intervention evaluation was the importance of the Navigator, with participants reporting that they felt supported by their

Navigator in the consultation planning, throughout the consultation with the clinician and following the consultation as someone with whom they could reflect on their situation. In this way, the Navigator was invaluable as an independent and objective facilitator for patients; literally a mechanism by which the patient could navigate their way through medical consultations. By acting in a way that enabled use of the evidence based strategies e.g. prompt list, coaching, use of summaries, Navigated patients were able to proactively participate in the decision making processes.

A unique feature of this study, and of the evaluation of this complex intervention, were the interviews undertaken with CRC patients receiving usual care, and therefore non-Navigated medical consultations. In this study, this provided a control comparison. Control participants, or usual care participants reported barriers in the consultation which prevented them from satisfying their information needs. When compared to experiences of Navigated participants, these barriers appear to have been overcome by the Navigation intervention. The communication barriers as reported by the CRC controls in this thesis, are largely consistent with those reported in the literature. For example, in a recent systematic review ( $n=45$ ) by Joseph-Williams et al. (2014), patients reported that lack of continuity of care through seeing different clinicians in clinic and a passive patient role in medical consultation were major barriers to involvement in their care. The authors report patients perceived asking questions as unacceptable and undermining of the clinician. This barrier to involvement in care is further supported when patients undervalue the expertise they bring to the consultation (Joseph-Williams et al., 2014). Frosch et al. (2012) in a focus group study conducted with patients ( $n=38$ ), reported that patients found it difficult to be heard by their clinician, resulting in them engaging in independent research to fill in information gaps. Furthermore, Frosch et al. (2012) reported that participants often brought a family member or friend to the

consultation appointment to help them recall the information provided. This was integral to accurate recall and memory, and to ensure that there was someone to debrief following the consultation.

This account of being unable to have questions answered in the consultation and having poor recall following the consultation was not present in the CRC and HGG Navigation participants. Participants exposed to the Navigation intervention in this thesis were able to make space in the consultation to ask their questions. The possibility of this occurring had been endorsed in the consultation planning discussion and by organising the content of the consultation plan. In addition, the consultation summaries were used after the consultation to help recall of events and as a document to share with family members and friends to keep them updated. In this way, the Navigation intervention in this study supports previous claims made in the literature with regards to the positive impact of decision support aids as outlined earlier in this thesis. The qualitative findings of Navigation support that two-way communication between patient and clinician was improved. Moreover, use of Navigation in situations where participants were receiving devastating diagnoses e.g. HGG, only appeared to assist people in coping with their situation and satisfaction with the care received. The Navigation consultation planning stage ensured all questions were identified and asked whilst the consultation summary and recording provided a record of the answers. In being able to utilise this intervention in consultations where distressing information was being discussed means that Navigation is well-suited to a situations where emotions are running high and as such, difficulties are inherent in formulating questions and recalling the answers given.

What is clear from this thesis is that whilst qualitative findings from this study offer positive evidence for the use and impact of Navigation, the quantitative results are less favourable.

Such a dichotomy in results is made reference to in a systematic review ( $n=33$ ) undertaken to assess the effects of decision making and communication interventions before medical consultations (Kinnersley et al., 2008). This review concluded that such interventions could significantly increase question asking and patient satisfaction. However, the authors concluded that these findings may not be enough to make notable changes to other quantifiable patient outcomes.

The final aspect of evaluation conducted in this thesis resulted from interviews with clinicians. This demonstrated a difference of opinion regarding the utility of Navigation within each cancer specific service. HGG clinicians were more in favour of Navigation when compared to CRC clinicians. When comparing this to other work in this area, for example, Belkora (2008) and Hacking et al. (2014), the perspective offered by HGG clinicians was comparable with other clinician's reports about the contribution that Navigation could make to care. Belkora et al. (2008) found clinicians (participant number not reported) endorsed the Navigation consultation plan as a tool to help patients organise and clarify questions prior to the consultation. Furthermore, the consultation plan gave clinicians a preview of patient need which could be used to strategise about how to conduct the appointment (Belkora et al., 2008). Hacking et al. (2014) also found that clinicians ( $n=4$ ) used the consultation plan to inform them about the patient's current understanding of their disease state and as a means to allow patients to communicate explicit preferences for treatment. This was ultimately seen to lead to a better quality of decision. Whilst these are positive and consensus findings, there is some note in this thesis and in Hacking et al.'s study (2014) that clinicians did not change their usual order of information provision to ensure that the necessary information required by the patient was relayed, but rather used the consultation plan as a checklist to ensure all questions were covered.



Perhaps one of the most notable findings to come from this thesis was the concern about the sustainability of Navigation within the NHS, particularly with regards to the costs involved in its delivery. Interestingly this is not raised in any of the original North American studies, but is raised by clinicians in the other UK studies, for example, Hacking et al. (2014). This may highlight a difference in decision making culture, or between the legal and financial frameworks of healthcare systems in the UK and the USA. This is an important area that requires further exploration and critique and is discussed further in the next section.

#### **10.6. Applicability of Navigation in the context of oncology care and health policy**

In this thesis, Navigation improved patient experience and satisfaction of medical consultation, information sharing and information understanding. Patients were positive in their evaluation of Navigation and, taken from the patient perspective, Navigation was useful in providing decision support. However, clinicians were divided in their views on Navigation, with HGG clinicians more supportive of the intervention than the CRC clinicians. For clinicians, the key differences lay in whether the Navigation consultation plan was seen as helpful or distracting in consultations and whether the additional time required to attend to patient-generated questions was valuable or pointless. This leads to consideration as to whether differences in cancer treatment pathways and/or distinctive organisational/professional cultures had bearing on these findings.

The two patient populations used to evaluate Navigation in this study shared the similarity of having cancer, but were dissimilar with regards to cancer prevalence, prognosis and disease trajectories. CRC being a common cancer (Ferlay et al., 2015), with a clear evidence-based treatment pathway (SIGN, 2015) and well identified areas of clinical and emotional information need (Van Mossel et al., 2012) was in contrast to HGG, a rare cancer

(Mirimanoff et al., 2006) with current treatments being more palliative than curative in nature (Wang & Jiang, 2013). As evidenced in both literature and participant/clinician reports in this thesis, each pathway holds distinctive and critical junctures for information sharing, and decision making (or lack of).

Empirical study on decision making assessment and support interventions are often tested in one cancer patient population with few studies exploring applicability across centres and in different stages of cancer (Carlson, Waller & Mitchell, 2012). Therefore, the ability to make qualitative comparisons and contrast patients' and clinicians' perspectives on Navigation across disease trajectories is a strength of this work. This reminds us of the difference in cancer care pathways, on the types of decisions to be made, and how this can impact on patient information needs. This must be acknowledged theoretically and empirically. In doing so, this not only provides understanding of patient information needs but also provides us with an ability to explain some of the differences in clinician perspectives on the applicability of Navigation.

HGG and CRC clinicians held different perspectives on Navigation. This requires exploration as to whether there were distinctive professional and/or organisational cultural factors that were influencing factors. In highlighting the professional differences between HGG and CRC, this study adds further weight to Lloyd et al's. (2013) assertion that the implementation and normalisation of SDM into [some] medical consultations remains challenging. However, many factors may impact on this. One qualitative study that interviewed 22 oncologists, reported that when treatment decisions were evidenced based with high success rates, oncologists made the assumption that patients wanted a good outcome and therefore were not consulted (Shepherd et al., 2011). Furthermore, oncologists described surgeons as less likely

to support patient involvement because their skills lay in manual dexterity (Shepherd et al., 2011). Perhaps another challenge for medical staff in developing a more positive and flexible approach to SDM is resultant from medical education in this area. Many patient-doctor interventions focus on developing the communication skills of doctors through using a standardised script approach. This is often doctor-led and medically driven (Fallowfield, Maguire, & Ramirez, 2004). Therefore, communication skills performance remains highly case specific (Baig, Violata, & Crutcher, 2009) implying that the transfer of communication skills from one patient encounter to another is neither obvious, nor easy. As identified in this thesis, attending to the specific needs of the patient in the context of their disease/illness pathway is important. This required clinicians to recognise the extent to which patients wish to be involved in their treatment (British Medical Journal, 2011) and have an awareness of, and confidence in using adaptable approaches and scripts in medical consultation.

A final area for exploration in this section is the sustainability of Navigation in the current health care system: an area of concern expressed by all clinicians. Even with strong policy drivers for SDM in health care (NICE, 2011; DH, 2011a; SIGN, 2015; Independent Cancer Taskforce, 2015), the reality of achieving SDM continues to be problematic. The goal of embedding shared information, shared evaluation, SDM and shared responsibilities (Coulter and Collins, 2011) into current health care practice needs much further work. In a paper outlining the challenges in achieving such a SDM culture change (Elwyn, Laitner, Coulter, Walker, Watson & Thomson, 2010), three conditions were identified as important: access to evidence-based information about treatment options; support for patients on balancing risk versus benefit of treatments; and a supportive culture that enables patient engagement. This last condition is interesting because while there has been much written about the development

and testing of interventions, less work has focussed on the sustainability of these interventions in practice.

With a clear ethical mandate to support SDM (Health Foundation, 2011) and detailed exploration of patient barriers (e.g. not knowing what questions to ask) with approaches to overcome these (Joseph-Williams et al., 2013), there is less exploration with regards to the organisational-related barriers, for example, lack of time for SDM, lack of medical continuity within clinics, and on-going funding for delivery of decision support intervention. These are all serious operational barriers to the on-going use of Navigation in the NHS.

Given the current resource constrained health care environment, these are important concerns requiring careful review. Future options worthy of consideration are that the same model of Navigation be delivered, but by trained volunteers or others e.g. medical students, who may be more affordable. However, it is worth noting that all clinicians involved in the qualitative evaluation study held the opinion that Navigators should be highly trained in order for the role to work effectively. Therefore any substitute Navigators would require suitable support and training. External funding sources were suggested by clinicians in this thesis, for example charitable funding, and this could be modelled on a similar approach to the Macmillan volunteers (<https://volunteering.macmillan.org.uk/>). An alternative option would be to look at different models of delivery. For example, in this study, the first Navigation appointment and first medical consultation held greatest impact with regards to decision making for patients. Even though this was a longitudinal study, patients and clinicians mainly spoke of the discussions and decisions in the first clinic appointment: all others were perceived as less significant. Consideration of this, and perhaps targeting the first medical consultation, may ease the funding burden whilst providing patients with the information and

decision making support required. An alternative approach would be to utilise specific and selected components of Navigation. Such initiatives could include having disease-specific pathway information, readable and accessible to all, use of summary clinic letters for patients following consultation and/or the provision of consultation recordings. A final option would be to consider utilisation of Navigation in patient pathways where there is greater potential for variance and increased options in decision making, as opposed to where standardised evidence-based guidelines exist for the treatment of certain cancers.

Although some junior clinicians reported being inhibited by medical consultations being recorded as part of the Navigation intervention, use of CD recordings may be an unrealised and underutilised approach in SDM, especially due to the availability of technology to undertake this. It is clear that this study has identified a need for summary and recording of the medical consultation. Although a written record was preferred by patients and clinicians, an audio-record should not be dismissed as a viable alternative.

With regards to the three conditions required for instituting SDM in healthcare (Elwyn et al., 2010), this thesis would suggest that attending to the last condition, that of developing a supportive culture that enables patient engagement will be critical to the on-going use of interventions, such as Navigation in the NHS. Indeed, future research should focus on the sustainability of such decision support interventions in practice.

SDM in health care constitutes the active discussion between and sharing of, expert information by the doctor (for example, risks and side effects of treatments) and the patient (for example, values and preferences for treatment). What is clear from this thesis is that achieving SDM in health care practice is complex, it requires multiple approaches,

engagement of clinical champions, and organisational support at the highest level in order to be sustainable. However, for SDM to be truly part of the fabric of health care, SDM should not stop at the clinic door. The principles of SDM need to be built in at every level of decision making, from cancer treatment options for an individual, through to cancer services commissioning for many individuals and communities.

### **10.7. Methodological critique of the study**

This thesis reports on evaluation of the effectiveness of Navigation, a complex intervention, in enhancing decision making quality over time when compared with usual care, in a cohort of CRC patients. It also explores the experiences of the Navigation intervention from the perspective of CRC and HGG patients and consulting clinicians. To undertake this, a mixed methodology using a pragmatic randomised control trial with nested qualitative studies was undertaken. Critique across this design is now offered through discussion on overall study design; the RCT; the qualitative studies; and the Navigation intervention.

A strength of this work was the use of quantitative and qualitative paradigms to meet the aims of the study. By providing methodological triangulation through use of RCT and qualitative interviews and using multiple perspectives, the results have provided a more expansive and detailed understanding of SDM in specific cancer contexts than previously known. Findings from the in-depth qualitative interviews provided explanation and new insights into the RCT results. This identified that Navigation in CRC and HGG cancer contexts may operate in ways different to other disease trajectories. It brings new insights to understanding how decisions are made, what is important to patients, and where the model of SDM sits within this arena.

Whilst use of a pragmatic longitudinal parallel-group RCT was a strength of the study, there were some identified limitations. The process of randomisation and recruitment were robust, given the confounding variables and constraints of what the trial population were experiencing i.e. receiving diagnosis of, and treatment for cancer. Whilst the potential for different commitment between intervention and control patients in RCT leading to a differential drop-out rate of patients (Campbell, 2000) is recognised, there may have been further sample bias in both arms of the RCT given that a high proportion of participants reached the threshold for borderline anxiety when compared with similar studies. A further limitation of this study, was that it was underpowered over time due to high attrition rates reported. Despite use of statistical assumptions and calculations to calculate the initial sample size, and attempts to increase recruitment through an extension on the time frame for recruitment, the sample population at the final time point (T3) was small.

Longitudinal measures were undertaken on primary (decision self-efficacy) and secondary (Decision Conflict, Decision Regret, Preparation for Decision Making, anxiety and depression) outcomes in order to evaluate the effectiveness of the Navigation intervention on the quality of decision making. There are limitations within this aspect of the trial design that merit acknowledgment. A more uniform pre-post design across all measures, including decision conflict, may have been more sensitive to identifying variations over time and provided a more rigorous and standardised approach to analysis. Given lack of statistical significance in the primary and, to an extent, secondary measures, this raises concern regarding the measures' validity and sensitivity. This is particularly so given that the interviews described a qualitatively different experience for patients when using Navigation compared to usual care.

Given results from the RCT in this thesis, other theories and variables, apart from decisional self-efficacy and decision conflict may need to be explored in future research. This may include utilising the concept of patient activation that explores how the knowledge, skills and confidence a person has, influences strategies to manage health. Measures have been developed from this work (Hibbard, Stockard, Mahoney & Tusler, 2004) that have high reliability in longitudinal study and may be more appropriate to use of Navigation in this setting. Furthermore, further work is required to determine whether the Preparation for Decision Making sub-scale used, was valid. Results demonstrated there may have been question bias towards the intervention arm, with less validity and applicability for control participants. This needs further work. In addition, the order of items per scale were not changed throughout the repeated completion of measures over the time points they were administered. The DSE and DCS in particular were administered four times to both trial arms over the nine months. This may have biased responses that are based in favour of recall rather than actual events.

A final concern in this longitudinal trial was contamination. It was noted by the Clinical Nurse Specialists that towards the end of the study, there was a perception amongst staff of a practice change in the CRC clinic. More patients were using self-made questions lists for appointments. It can only be inferred that staff were influenced by the study, integrating advice to patients about preparing for consultation, and this may have influenced study results.

With regards to the qualitative component of this evaluation study, prospective qualitative interviews were conducted with the CRC cohort of patients, patients with HGG, and their consulting clinicians. Due to natural attrition in the patient cohorts, this resulted in a small



sample size. Whilst this is in keeping with qualitative work, this may not have been adequate to capture the full range of experiences. However, data saturation was evident in analysis. With data collection limited to two clinics in one tertiary site, findings are specific to these populations and transferability of findings limited to this context.

Both a strength and a limitation of this study was the longitudinal nature of the evaluation undertaken. As the concern regarding contamination was highlighted earlier, such culture change could have impacted on participant's experiences and on their accounts of decision making and consultation. A further limitation to be noted is that as a longitudinal study, it is acknowledged that the researcher-participant relationship changed over time. With recognised potential to impact on rigorous data collection, details have been given in earlier methods chapters as to how the researcher adopted a reflexive position within this study.

Collecting data through interview provided one perspective of social interaction in the consultation. It may not have provided an accurate representation of all aspects of decision making in medical consultation. Further research may consider interview with other data sources e.g. nurses and carers, and using other data collection methods, e.g. field observation in ethnography, to provide a more comprehensive description of the social phenomena of decision making with CRC and HGG patients and clinicians.

Finally, limitations with the intervention tool itself merit brief discussion. As stated previously, Navigation is a complex intervention that consists of the three evidence-based practices of question listing, audio recording and summarising, combined into one patient-centred intervention. A key strength of the Navigation intervention therefore is that it has strong theoretical and empirical underpinning. The study protocol and operating procedures

used in this evaluation work were detailed and robust. Using and complying with these procedures in the conduct of the study ensured that the integrity of the study design was maintained. However, it must be acknowledged that the Navigation intervention was delivered by two Navigators. In this study these were individuals who were given training in Navigation and supported throughout by clinical supervision. Navigators in this study were educated and had professional backgrounds in psychology (one at doctoral level). Furthermore, it could be suggested that through on-going supervision, not only were the Navigators skilled and educated individuals, but that they had insight and compassion into the experience of study participants. Whilst this had potential to contribute to the complex relationships known to exist between an intervention and the implementation fidelity, it must be noted that even in such a supportive implementation environment, no significant impact on the primary and secondary outcome measures were found.

### **10.8. Summary of Results**

Drawing on the literature, this chapter has discussed key results from the evaluation of Navigation in the CRC and HGG patients. In this, the importance of this work with regards to contributing to knowledge about the two cancer populations and their respective disease trajectories has been explored. This mixed methodology study has highlighted the challenges of shared decision making and identified how information barriers in the medical consultation can be addressed through use of Navigation. This chapter has identified the contribution that the Navigation intervention has made to improve the experience of decision making from the perspective of patients, but also the significant challenges to sustaining and embedding decision support aids in practice. In the next and final chapter, the contributions that this work makes to theoretical knowledge and methodological understanding will be presented together with the implications that this study has for healthcare practice and policy.

## **Chapter 11: Conclusion**

### **11.1. Introduction**

This primary research into the effectiveness of the Navigation intervention in enhancing decision making quality and the experience of patients and clinicians in its use, has demonstrated that Navigation has more impact on the process of decision making, rather than the outcome of decision making per se. Contextual factors that challenge the use of Navigation in health care consultations include: the nature of decisions to be made in CRC and HGG treatment pathways; on-going cultural perceptions about patient ‘passivity’ and a dominant medical role within consultation; and resource constraints that may hinder the sustained use of Navigation in the current health service.

In drawing attention to these complex inter-relating factors, this research has brought to the fore unrecognised assumptions made about decision making processes in medical consultations and patient goals when meeting with medical staff about treatment options. This evaluation has raised questions about the portability of interventions developed in one international clinical setting to another and the generalisability of outcome measures to determine the impact of decision support interventions in new research settings.

This study has therefore demonstrated important new ways of understanding and made contribution to knowledge, methodology and method as well as to health policy and practice arenas. The substantial contribution in each of these areas will now be made clear.

## **11.2. Contribution to knowledge**

Results of this evaluation make an important contribution to knowledge by providing new perspectives in understanding the specific challenges and needs of cancer populations that, to date, have received little previous empirical review. In exploring the use of Navigation in CRC and HGG populations, a more in-depth knowledge of the discrete disease and treatment pathways and the associated decision-making processes has been raised. This study advances important theoretical knowledge of the complex interaction between medical treatment pathway, patient choice and shared decision making, thereby identifying what decisions can and need to be made and by whom.

Further to this, the evaluation distinguishes a shared decision making model focussing on patient contribution to the decision making processes, from one with a focus on decisional outcome. In making clear how Navigation enables greater patient engagement in decision making processes through the asking of questions, facilitating information recall and understanding of consultation, traditional models that focus on outcomes of shared decision making are contested.

In challenging how shared decision making has been described in the literature to date, this research makes an original contribution to the future development of theoretical models and concepts of shared decision making in health care, and for the theoretical frameworks and underpinning of similar decision support aids, such as Navigation. It also raises questions as to whether shared decision making is the a priori concept for consideration in this area, or whether other concepts, including patient empowerment and engagement are more fitting.

### **11.3. Contribution to methodology and method**

This study contributes to understanding the effectiveness of Navigation by using a more complex study design and more detailed measures than previously described in stand-alone quantitative or qualitative evaluation of the intervention. In offering an intricate mixed methods study, this empirical piece is: the first to undertake a longitudinal approach to the evaluation; unique in undertaking a RCT approach to Navigation evaluation; pioneering in including a bespoke qualitative evaluation of Navigation from the perspective of clinicians and a usual care cohort; and the only study to use and test new measures, for example Preparation For Decision Making, and in previously unexplored samples, for example CRC and HGG populations.

In undertaking mixed methods research, this study has drawn attention to the benefits and explanatory power that qualitative study can bring to quantitative work. In this work, whilst null hypotheses regarding the effectiveness of Navigation on primary and secondary outcomes were confirmed, findings from the qualitative evaluation studies gave understanding to the underlying decision making processes in medical consultation and of the impact of Navigation on the experiences of patients and clinicians.

Given the results of the RCT, this evaluation has also challenged previous assumptions in the literature about measures perceived as important to assess decision making efficacy in use of decision aids in this context. With previous research describing use of outcomes focussed measures, this study suggests that different conceptualisations of shared decision making and therefore different process oriented measures and scale are required. This is an important new and original finding that has implications for understanding the evaluation of Navigation in other health care settings.

Through the above areas, this research makes a substantial contribution to current understanding on the Navigation intervention, and on the methodological and methods challenges in evaluating complex interventions in this area.

#### **11.4. Implications for health care practice and policy**

Implications for health care practice arising from this study identify that there is a need for critical review of the clinician patient relationship with regards to shared decision making models. More flexible frameworks need to be developed and acknowledged than meet the needs of patients in given health care circumstances. Results from this evaluation suggest development of health care practice and policy that supports the needs of individual patients to engage in decision making processes, rather than engage in ultimate treatment decision making outcomes, as highlighted in this study, is called for. Interventions that work towards meeting patient needs for information gathering and improved information management, essential aspects of Navigation, including improved recall to support their own needs and those of others, should be recognised as important. Therefore, strategies that promote process quality areas including; preparation for consultation, raising questions in consultation and having accurate recall of information, should be profiled alongside making treatment decisions in local clinical practice initiatives, as well as in national health care policy.

In order to promote information sharing and information exchange at all levels of health care delivery, a needs assessment is required to determine the area of information that patients require and integrate these with the medical agenda for consultation. The importance of written records, an implicit component of Navigation profiled in the findings of this study, also needs acknowledgment and consideration for wider adoption.

Decision making in cancer settings requires re-conceptualisation to ensure significant commitment is made to the principles of shared decision making that engage patient and carer in the process and outcome of decision making with clinicians. This would require an improved recognition of the cancer trajectories and the associated decisions to be made. It would also require a realistic distinction of treatment decisions made by clinicians and those available to be made by patients. The principles that underpin such an understanding must then be consistently integrated across local and government policy. New health policy and clinical guidelines should specifically address how information needs are met and incorporate the principles of shared decision making that embrace both clinician and patient perspectives.

Finally, use of decision support interventions, such as Navigation will only become embedded in healthcare if resource is identified to support implementation and sustainability of these currently resource-intensive tools. As clearly identified in this study, there is concern with regards to the adoption of Navigation in current care delivery. Whilst undoubtedly an expanding body of empirical work demonstrating impact and efficacy of such interventions will add support to this. Further work is required to determine case of need, cost benefit and risk assessment in use of Navigation and exploration of alternative models of implementation that give value for money.

## **11.5. Conclusion**

Cancer consultations between patients and cancer clinicians and decisions that inform treatment decision making are processes with associated human experiences. These cannot be conceptualised as events. Whilst models of shared decision making continue to be highly profiled in cancer health policy strategies, information exchange and use of decision aids in medical practice, remains problematic.

This evaluation study has demonstrated that Navigation has more impact on the process of decision making, rather than outcome of decisions per se. Patients in this study did not want autonomy for the treatment decision but preferred the experts in their cancer care to undertake this responsibility. However, participants still needed to be able to feel involved in the process, to understand their situation and what the decisions meant to them and their individual circumstances. In this study, Navigation is a tool that enables patient engagement at the level of information exchange.

A more nuanced understanding of different cancer pathways and the specific decisions to be made, together with greater consideration of patient priorities for information and engagement, may inform a more targeted and sustained use of decision support interventions, such as Navigation, in cancer care.



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## **Appendices**

## Appendix 1: Letter of Ethical approval

Lothian NHS Board

South East Scotland  
Research  
Ethics Committee 03  
Waverley Gate  
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03 November 2010  
Dr. Belinda Hacking  
Consultant Clinical Psychologist  
NHS Lothian  
Edinburgh Cancer Centre  
Crewe Road, Edinburgh  
EH4 2XU

Dear Dr. Hacking

**Study Title: Informing and involving newly diagnosed Malignant Brain tumour and Colorectal cancer patients in their cancer health care using a Patient Information Navigator.**

REC reference number: 10/S1103/47 Protocol number: n.a

Thank you for your letter of 01 November 2010, responding to the Committee's request for further information on the above research and submitting revised documentation.

### Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

### Ethical review of research sites



Headquarters Waverley Gate, 2-4 Waterloo Place, Edinburgh EH1 3EG  
Chair Dr Charles J Winstanley chief Executive Professor James J  
Barbour O.B.E. Lothian NHS Board is the common name of Lothian Health

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see “Conditions of the favourable opinion” below).

## Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

**Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.**

For NHS research sites only, management permission for research (“R&D approval”) should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

*Where the only involvement of the NHS organisation is as a Participant Identification Centre (PIC), management permission for research is not required but the R&D office should be notified of the study and agree to the organisation’s involvement. Guidance on procedures for PICs is available in IRAS. Further advice should be sought from the R&D office where necessary.*

*Sponsors are not required to notify the Committee of approvals from host organisations.*

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

### Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Investigator CV	Wallace	13 September 2010
Investigator CV	Shepherd	13 September 2010
Investigator CV	Hacking	13 September 2010
Protocol	2	01 November 2010
Patient letter enclosing summary of consultation	1	13 September 2010
GP Feedback Request Form Malignant Brain Tumour	1	13 September 2010
Bowel Cancer Focus Group Chart		
Patient letter allocating to Colorectal intervention group	1	13 September 2010
Colorectal ?s patients to ask doctor	1	13 September 2010
colorectal websites	1	13 September 2010



Wording to invite newly diagnosed colorectal cancer patients	1	13 September 2010
GP Feedback Request Form	2	01 November 2010
Services Evaluation	2	01 November 2010
Booklet cover Information about yourself	2	01 November 2010
REC application		27 September 2010
Covering Letter		23 September 2010
Letter from Sponsor		20 September 2010

Interview Schedules/Topic Guides	1	13 September 2010
Questionnaire: Health Survey scoring demonstration	1	13 September 2010
Letter of invitation to participant	1 Colorectal	13 September 2010
Letter of invitation to participant	1 Neuroncology	13 September 2010
GP/Consultant Information Sheets	1 Colorectal intervention group	13 September 2010
GP/Consultant Information Sheets	1 Colorectal Control	13 September 2010
GP/Consultant Information Sheets	1 Neuroncology	13 September 2010
Participant Information Sheet: PIS Colorectal patients		
Participant Information Sheet: Healthcare Professional Info Sheet - Colorectal Patients	1	13 September 2010
Participant Information Sheet: Healthcare Professional Info Sheet - Neurological patients	1	13 September 2010
Patient letter confirming Consultation Planning appointment	1	13 September 2010
Evidence of insurance or indemnity		
Neuro Focus Group		
Participant Information Sheet: PIS Neuro		
Patient letter allocating to Colorectal control group	1	13 September 2010
Patient letter re volunteering Neuro group		13 September 2010
Patient letter re volunteering Neuro group		
Cover referring to which questionnaires sent	1	13 September 2010
Questionnaire: Patient Activation Measure	1	13 September 2010
Questionnaire: ISQ	1	13 September 2010
Questionnaire: Decisional Regret	1	13 September 2010
Questionnaire: MACs	1	13 September 2010
Questionnaire: Distress Thermometer	2	13 September 2010
Neuro-onc ?s to ask doctor		13 September 2010
Neuro websites		13 September 1998
Wording to invite newly diagnosed Malignant Brain tumour patients	1	13 September 2010
Evidence of insurance or indemnity	1 AON commercial Insurance	30 July 2010

Response to Request for Further Information		01 November 2010
Participant Consent Form: PCF Colorectal Patients	2	01 November 2010
Participant Consent Form: PCF Neuro-oncology	2	01 November 2010
Participant Consent Form: PCF Consultants	2	01 November 2010
Questionnaire: Satisfaction with Consultation Scale	2	01 November 2010
Questionnaire: Anxiety & Depression Scale	2	01 November 2010
Questionnaire: Confidence in Decision Making	2	01 November 2010
Questionnaire: Decisional Conflict Scale	2	01 November 2010
Questionnaire: Patient Generated Index of Quality of Life	2	01 November 2010
Questionnaire: Feedback	2	01 November 2010

## Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

## Appendix 2: The TIDieR (Template for Intervention Description and Replication) Checklist\*: Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other <sup>†</sup> (details)
1.	<b>BRIEF NAME</b> Provide the name or a phrase that describes the intervention.	p80	
	<b>WHY</b> Describe any rationale, theory, or goal of the elements essential to the intervention.	p80-81	
2.	<b>WHAT</b> Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL). Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	p82-86	
4.	<b>WHO PROVIDED</b> For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	p87-90	
5.	<b>HOW</b> Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	p82-86	
6.	<b>WHERE</b> Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	p86	
7.			

	<p><b>WHEN and HOW MUCH</b></p> <p>8. Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose. _____p91-96_____</p> <p><b>TAILORING</b></p> <p>9. If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how. _____n/a_____</p> <p><b>MODIFICATIONS</b></p> <p>10.* If the intervention was modified during the course of the study, describe the changes (what, why, when, and how). _____n/a_____</p> <p><b>HOW WELL</b></p> <p>11. Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them. _____n/a_____</p> <p>12.* Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned. _____n/a_____</p>
--	--

**\*\* Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use ‘?’ if information about the element is not reported/not sufficiently reported.

## Appendix 3: SCOPED framework

### Patient Information Navigation Study

Here are some questions which you *might* want to ask your doctor during your upcoming appointment. If you are uncomfortable with any of the questions below please let us know and we will not address them.

#### **Situation: Key facts about my condition: Do I have any questions surrounding:**

- My diagnosis or my condition?
- My test results?
- Do I have any concerns about how treatment might affect other medications, or medical conditions that I have?
- Is there anything significant or important about my situation which I would like my doctor to know?

#### **Choices: What are my choices?**

- What treatment is available to me?
- Are there any medical/drug trials available to me?
- How will my lifestyle be affected by my choices?

#### **Objectives: Goals, Preference and Priorities**

- What are my goals for my appointment with my doctor?
- What are my goals for treatment?
- Regarding my quality of life; what do I want to continue as normal? For example my work, my hobbies, my daily activities e.g. driving, body image, sexuality, child-rearing?
- Have I any preferences about, e.g. Appointment times?
- Would I like survival/complications to be explained to me? And how?

#### **People: Roles and Responsibilities in Decision Making**

- Who do I want to have a voice in influencing my decisions?
- What kind of information do I want my doctor to give me (i.e. make a recommendation, and/or make a decision for me?)
- How would I like the doctor to explain things to me? For example, in layman's (understandable) terms or in medical language?

#### **Evaluation (Main Questions):**

Do I have any questions surrounding:

- My prognosis with/without any further treatment?
- How my choices will affect :
  - o Survival?
  - o Complications?
  - o Side effects?
  - o How my treatment choices will affect my quality of life in the long-term?

#### **Decisions: Which choice is best and what are the next steps.**

- Who needs to do what, when, where, how and why?
- Are there any websites and/or support groups for further information/advice/support?

**Appendix 4: An example of a consultation plan, for a person with HGG.**

<b>Situation</b>	<ul style="list-style-type: none"> <li>I was taken into ICU and had to be operated on immediately. I don't remember what happened. <b>Can you tell me what happened to me, and what happened during surgery?</b></li> <li>I have lumps on my head, swelling at the back of my head, stiffness and pain in my neck, and a rash from the base of my neck to the front. My eyes also go a bit cloudily now and again. My right eye isn't very good right now. <b>Are these all caused by the surgery?</b></li> <li><b>How long will it be until my head stops feeling numb?</b></li> <li><b>Will I be ok to lie on the side where my scar is?</b></li> </ul>
<b>Choices</b>	<ul style="list-style-type: none"> <li><b>If the tumour is cancerous, I think I might have to have chemotherapy or radiotherapy - is this correct?</b></li> <li><b>Are there any other treatments available rather than chemotherapy or radiotherapy? E.g. a drug trial?</b></li> </ul>
<b>Objectives</b>	<ul style="list-style-type: none"> <li>I would rather you didn't use medical terms unless you can explain them to me so that I can understand them.</li> <li>I'm really worried about the effects of treatment (e.g. feeling sick and ill) and the problem coming back.</li> <li>If I need treatment, I'd rather have something other than chemotherapy if possible.</li> </ul>
<b>People</b>	<ul style="list-style-type: none"> <li>My fiancé ...., and my family for support</li> <li>Consultant to explain things to me.</li> </ul>
<b>Evaluation</b>	<ul style="list-style-type: none"> <li><b>What are the results from surgery?</b></li> <li><b>What happens next?</b></li> <li><b>What can I do to make myself feel better now?</b></li> <li><b>If I have to have treatment what can I do to stop myself feeling ill during treatment?</b></li> <li><b>Would it be ok to go out and walk about (get back to normal)?</b></li> </ul>
<b>Decisions</b>	<ul style="list-style-type: none"> <li>I am happy to take the recommended treatment.</li> <li>I would like to know who to talk to for support.</li> </ul>

## Appendix 5: An example of a consultation summary from an initial consultation

<b>Situation</b>	<ul style="list-style-type: none"> <li>You had a generalised seizure on the night that you came into hospital.</li> <li>The mass in your head was putting a lot of pressure on your brain, causing a lot of swelling, so your surgery had to be done in a hurry to relieve the pressure.</li> <li>The surgeon, ....., took away as much of the tumour as he could during surgery, so that your brain is in a better position. This is called 'debulking'. We cannot take the rest of the tumour out as it may paralyse you.</li> <li>The swelling is due to a little bit of fluid which has collected around the brain, this will go in time.</li> <li>You will be ok to lie on the side where your scar is as it looks nicely healed.</li> <li>The numbness in your head takes a long time to heal as the nerves have been cut during surgery. The nerves now need to join up again. They can several months to heal.</li> <li>Your results tell us that you have a brain tumour. It is malignant which means it is fast growing.</li> <li>The treatment will not get rid of this tumour. It is terminal.</li> </ul>
<b>Choices</b>	<p>The treatments that are recommended to you are:</p> <p><b>Radiotherapy</b></p> <ul style="list-style-type: none"> <li>Radiotherapy treatment is strongly advised to you.</li> <li>This is x-ray treatment.</li> <li>We use 3-4 x-ray beams to concentrate the x ray beams onto the affected tissue. You will not feel anything during treatment.</li> <li>You will have radiotherapy treatment <b>once a day for 6 weeks</b> at the hospital. Each treatment lasts for 15 minutes every day.</li> </ul> <p><b>Chemotherapy</b></p> <ul style="list-style-type: none"> <li>We can also give chemotherapy treatment, in tablet form.</li> <li>You need to take the chemotherapy tablets at the same time as the radiotherapy.</li> <li>You will take the tablets everyday in the morning.</li> </ul> <p><b>For someone of your age, it is recommended that you have both chemotherapy and radiotherapy treatment, as this is the most effective combination.</b></p>
<b>Objectives</b>	<ul style="list-style-type: none"> <li>To give you the best treatment available.</li> <li>Treatment can make you live longer and give you good quality time to do things that you want to do with your friends and family. Without treatment, your survival could be really quite short (a few months, compared to a few years if you have treatment).</li> </ul>
<b>People</b>	<ul style="list-style-type: none"> <li>....., your fiancé.</li> <li>Dr ....., Consultant.</li> <li>... Navigator.</li> <li>Your GP is a good source of support – try and keep in touch with them regularly.</li> </ul>
<b>Evaluation</b>	<p><b>Radiotherapy</b></p> <ul style="list-style-type: none"> <li>We will need to make a mask for you. It is made of plastic, which we warm up and it then goes floppy.</li> <li>For treatment, you lie on a couch and you are then clipped down using the mask. It is tight, but it isn't too bad.</li> <li>We will do a CT scan and MRI scan. These will be put together (overlapped) onto a computer. They will then draw around the hole left behind after surgery and any bits that are lighting up and a rim of about 2 cm around where the tumour was taken out, as there could be cells left behind.</li> <li>Once the scans are done, the planning will occur within 2 weeks and then</li> </ul>

	<p>treatment will start in around 4 weeks' time, to give you more time to recover from the operation.</p> <ul style="list-style-type: none"> <li>• Radiotherapy has to be planned really carefully which is why it takes some time, but we'll try to get it done as quickly as we can.</li> <li>• Most people cope with radiotherapy really well.</li> <li>• However, it will cause tiredness, and it can make people quite headachy and sick</li> <li>• You will lose some of your hair, mainly towards the front of the head. It might not grow back quite as thickly.</li> </ul> <p><b>Chemotherapy</b></p> <ul style="list-style-type: none"> <li>• Chemotherapy can make you have sickness, but we will give you anti sickness pills.</li> <li>• It can affect your immunity, so we are worried about your teeth. We'll see if we can get dentist to check you don't have a source of infection during the treatment.</li> <li>• You can go out and walk around as long as you take someone the first time you go out.</li> </ul>
<b>Decisions</b>	<p><b><u>Decisions Made During the Consultation:</u></b></p> <ul style="list-style-type: none"> <li>• Dr ..... has put in a request for you to have radiotherapy. You will be asked to sign a consent form for radiotherapy when you come up to have your scans</li> <li>• You have decided to have chemotherapy too.</li> </ul> <p><b><u>Next Steps</u></b></p> <p>Planning for radiotherapy treatment – CT scan and MRI scan. You will be sent a letter in the post with your appointment times.</p>





## Appendix 6: CONSORT 2010 checklist of information to include when reporting a randomised trial\*

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>	1a	Identification as a randomised trial in the title	iv-v
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	iv-v
<b>Introduction</b> Background and objectives	2a	Scientific background and explanation of rationale	Chapter 2 &3 p.8
	2b	Specific objectives or hypotheses	
<b>Methods</b> Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	p.102
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	p.101
Participants	4a	Eligibility criteria for participants	p.103
	4b	Settings and locations where the data were collected	p.78
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Refer to TIDieR checklist
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	p.108-116
Sample size	6b	Any changes to trial outcomes after the trial commenced, with reasons	Na
	7a	How sample size was determined	p.116
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Na

Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	p.117
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	p.117
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Na
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	p.117
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Na
	11b	If relevant, description of the similarity of interventions	na
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	p.118-120
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	na
<b>Results</b>			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	p. 124-127
	13b	For each group, losses and exclusions after randomisation, together with reasons	p.124-127
Recruitment	14a	Dates defining the periods of recruitment and follow-up	p.121
	14b	Why the trial ended or was stopped	Na
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	p.126
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	p. 121-147

Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	p. 121-147
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	na
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	na
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	na
<b>Discussion</b>			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	p. 260
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	p. 226-264
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	p. 226-264
<b>Other information</b>			
Registration	23	Registration number and name of trial registry	na
Protocol	24	Where the full trial protocol can be accessed, if available	na
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

\*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).

## Appendix 7: Invitation sheet, CRC trial.

On headed notepaper

Clinical Psychology Office

Edinburgh Cancer Centre

Edinburgh, EH4 2XU

Tel: 0131 537 1247

### Patient Information Navigation Study

Dear \_\_\_\_\_,

We are currently running a study at the (name of centre) in the Colorectal Clinic. You are receiving this information because you have an upcoming appointment for Thursday.

The study is called the **Patient Information Navigation** study.

Included in this envelope is an information sheet, take some time to read over this and decide if the study is something that you think would like to take part in. Also enclosed is a consent form and questionnaire, you do not need to fill these in at the moment but if you think you would like to take part in the study please look over them. A researcher will call you to answer any of your questions and guide you through the process. Taking part is voluntary and it will not affect your healthcare if you do not wish to participate.

Please feel free to get in touch sooner if you have any questions.

Thank you for taking the time to read about this study.

Yours sincerely

Sarah Shepherd

Study Evaluator

Tel:

## Appendix 8: Information Sheet, CRC trial



### Patient Information Navigation STUDY INFORMATION SHEET



Here at the Edinburgh Cancer centre, we are inviting you to take part in a research trial. **This study is trialling Navigation**, a way of helping patients gain and remember information about their health care. Navigation has been successful in the USA with breast cancer patients and in Scotland with prostate cancer patients. This study is evaluating if Navigation works for patients with colorectal cancer. Our results will allow us to inform practice in Scotland.

#### Why Have I Been Invited?

You have been asked to take part because you have an **upcoming first time clinic appointment at the Edinburgh cancer centre in the colorectal clinic**, and a diagnosis of colorectal cancer.

#### Navigation is made up of 3 parts:

- (1) Help with making a **list of questions** and concerns for your next hospital consultation,
- (2) Recording the hospital consultation and being given a copy of the recording on a **CD**,
- (3) Navigator takes **notes** of all the key points spoken about in the consultation and sends these to you, your GP and your consultant.

#### Do I Have To Take Part?

Taking part is completely voluntary. It is up to you to decide whether or not to take part. Your decision to take part or not, does not affect your treatment in any way.

#### What if I decide to take part?

**Consent process:** If you do decide to take part you will be asked to sign a consent form. You will need to agree to the points on the consent form (included in your pack) with the researcher over the telephone. If you decide to participate now but change your mind later you can withdraw from the study at any point, without giving any reason, without your medical care or legal rights being affected. If you do consent you will be **randomised** to one of two groups.

#### What is Randomisation?

To find out if 'Navigation' is successful when you consent you will be randomly put into one of two available groups. These are:

1. Navigation OR
2. Monitored care

As we do not know if Navigation can work successfully in the colorectal clinic you are entered into only one of the two groups. The computer will put you into one of these groups. The study team has no control over which group you are entered into. One group will receive the Navigation service (Navigation) and the other group will not (monitored care).

#### What do I have to do?

Volunteer some of your time to be part of this evaluation:

**Navigation:** The navigator will telephone you to make a list of questions; this takes about 30 minutes. Fill in 8 questionnaires over the next 9 months. Take part in an interview.

**Monitored Care:** You **do not** receive the Navigation service. Fill in 5 questionnaires over 9 months. Take part in an interview.

**Questionnaires will each take 10-20 minutes, and will be sent to your home, with a stamped addressed envelope to send them back.**

**Interviews:** If you would like to take part in an interview to tell us about your experience at the hospital this will be arranged at your convenience. Interviews can take place at the hospital or at home, whichever is more suitable. Telephone interviews can be arranged. Interviews will be at the end of the study.



Sarah Shepherd | [sarah.c.shepherd@luht.scot.nhs.uk](mailto:sarah.c.shepherd@luht.scot.nhs.uk) | x31247 | 0131 537 1247



### **What is the difference between navigation and monitored care?**

#### **NAVIGATION GROUP:**

If you are entered into the Navigation group, A Navigator will telephone you. This is a member of staff trained to help you make a list of questions, audio record your hospital consultation, give you a CD of the consultation, and take medically correct notes for you.

Navigators **do not provide** information but can signpost you to important sources or people.

Navigators telephone you and encourage and prompt you to develop questions and information for your doctor. This can take 30 minutes.

The doctor then has a chance to view your questions and uses them as a checklist in the appointment to make sure all your points have been covered.

The navigator comes with you to the appointment, audio-records the consultation and takes notes.

When you leave your consultation you will be given a CD of the appointment and a few days later a typed summary will be sent in the post. This will also be sent to your consultant and if you wish your GP.

This will happen for **up to 4 different appointments** over the next 6 months, if this is applicable to your situation.

We will ask you to fill in 8 questionnaires along the way so we can monitor how you are doing.

#### **MONITORED CARE:**

If you are assigned this group you **do not** receive the navigation service. You will only fill in questionnaires sent to your house. The study will monitor how you are doing with 5 sets of questionnaires over 9 months.

### **Potential benefits and disadvantages to taking part**

This study will help us improve the quality of our services. By taking part, you may be provided with a summary and CD of your meeting. We will also monitor you via the questionnaires. If any questions in the questionnaires make you feel uncomfortable or upset, you are free to decline to answer, or discontinue your participation. You can also visit the support services available at the Macmillan Centre. A list of agencies can be provided on request.

#### **What if I would like to withdraw?**

We may still use the data that you have given, however, you are free to withdraw from the evaluation altogether and we can remove all your data if you ask us to. If you choose to do this you do not have to give a reason for your choice. Your treatment will not be affected in any way by withdrawing from the study.

#### **What will happen to the results of the study?**

All participants will be offered a short newsletter at the end of the study. The results of the study will be on the SCAN website, in research journals, professional publications and presentations made at relevant conferences. All results will be reported anonymously.

#### **Who is organising and funding the study?**

The study is funded by the Edinburgh Cancer Centre in collaboration with Macmillan Cancer Support and Coventry University. If you have any concerns or questions about this evaluation or the way it has been carried out, contact the principal researcher Dr. Belinda Hacking (0131)537 1241.

#### **Who has reviewed the study?**

This study has been reviewed and passed by Lothian Research Ethics Committee 10/S1103/47.

THANK YOU FOR READING THIS INFORMATION SHEET. A RESEARCHER WILL TELEPHONE YOU SHORTLY.

## Appendix 9: Consent form, CRC trial



Version 3, Nov 23, 2010



Patient ID

### **CONSENT FORM**

#### **Title of project: Patient Information Navigation Study**

Principal Investigator: Dr. Belinda Hacking

	Please initial boxes
1. I confirm that I have read and understand the information sheet (Version 1) for the above study and have had the opportunity to ask questions.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3. I agree that the written information I provide can be stored with my name removed from all records and used in the presentation of the research. My data will not be used to identify me	
4. I agree to take part in one interview at the end of the study to talk about my experience of consultations.	
5. I agree that the audio information I provide in the interview can be audio taped, transcribed, stored with my name removed from all records and my words used in the presentation of the research. My words will not be used to identify me.	
6. I agree to take part in the study	
7. I agree for my GP to be informed about my participation in this study AND for a consultation summary to be sent to my GP (you do not have to initial this box, if you would prefer NOT to have your GP informed of your participation).	
8. I allow NHS Lothian, as a sponsor of this study to access my medical records to ensure the study is being run correctly.	
9. I would like to be informed of the results	

\_\_\_\_\_  
Name of Patient

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Principal Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

*1 Copy for the patient, 1 Copy for the principal investigator*

*Patient information navigation study · Clinical Psychology in Oncology · Edinburgh Cancer Centre · Western General Hospital · Tel: 01315371247 · shephe17@uni.coventry.ac.uk*

## Appendix 10: Demographics

T1 version 2 Nov 2010

2

Patient code:

### Information about yourself

Instructions: Please answer ALL questions by TICKING the relevant box, unless the question specifies otherwise

**1. Date of Birth (DD/MM/YYYY)**

**2. What sex are you?**

☐ *Female*

☐ *Male*

**3. What is your ethnic origin?**

☐ *White*

☐ *Mixed ethnicity*

☐ *Asian or Asian British*

☐ *Black or Black British*

☐ *Chinese*

☐ *Other ethnic group (please specify below)*

**4. What is the highest level of formal education you have completed?**

- ☐ Left school before 15
- ☐ Secondary education to age 15/16/17/18 (circle)
- ☐ College or specialised training beyond 18
- ☐ University, graduate school or equivalent
- ☐ Other, Please specify \_\_\_\_\_

**5. What is your current marital status?**

- ☐ Married or living as married
- ☐ Divorced
- ☐ Separated
- ☐ Widowed
- ☐ Single (never married)

P.T.O



6. What is your current employment status? MARK ALL THAT APPLY

- ☐ Working full time
- ☐ Working part time
- ☐ Retired
- ☐ Unemployed
- ☐ Student
- ☐ Other, please specify:

If unemployed or retired was this a direct result of your illness? YES /NO

**7. Please specify what is / was your main employment?**

[illegible]

P.T.O

## Appendix 11: Decision Self Efficacy Measure

T1 version 2 Nov 2010

6

Patient code:

### Confidence in Decision Making

Below are listed some things involved in making an informed choice. Please show how confident you feel in doing these things by putting a tick next to the number that best describes how confident you feel from **0 (not at all confident) to 4 (very confident)** for each question below. Please answer **all** the questions. Please tick **only one** response for each question. Thank you.

I feel confident that I can...	Not at all confident	Very confident
1. Get the facts about the medication choices available to me.	0 <input type="checkbox"/>	1 <input type="checkbox"/>
2. Get the facts about the benefits of each choice.	2 <input type="checkbox"/>	3 <input type="checkbox"/>
3. Get the facts about the risks and side effects of each choice.	4 <input type="checkbox"/>	5 <input type="checkbox"/>
4. Understand the information enough to be able to make a choice.	6 <input type="checkbox"/>	7 <input type="checkbox"/>
5. Ask questions without feeling silly.	8 <input type="checkbox"/>	9 <input type="checkbox"/>
6. Express my concerns about each choice.	10 <input type="checkbox"/>	11 <input type="checkbox"/>
7. Ask for advice.	12 <input type="checkbox"/>	13 <input type="checkbox"/>
8. Figure out the choice that suits me best.	14 <input type="checkbox"/>	15 <input type="checkbox"/>
9. Handle unwanted pressure from others in making choices.	16 <input type="checkbox"/>	17 <input type="checkbox"/>
10. Let the clinic team know what's best for me.	18 <input type="checkbox"/>	19 <input type="checkbox"/>
11. Delay my decision if I feel I need more time.	20 <input type="checkbox"/>	21 <input type="checkbox"/>

P.T.O

## Appendix 12: Decision Conflict Measure

T3I  
Version2 Nov2010

Patient code:

3

### Decisional Conflict Scale

Now, thinking about the choice [you just made, you made, you are about to make] please look at the following comments made by some people when making decisions.

Please show how strongly you agree or disagree with these statements by ticking the appropriate box, indicating how far it applies to you. For example, if the statement definitely does apply to you, then you should tick the first box in the column.

	<i>Strongly Agree</i>	<i>Agree</i>	<i>Neither Agree Nor Disagree</i>	<i>Disagree</i>	<i>Strongly Disagree</i>
1. This decision is easy for me to make.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I am sure what to do in this decision.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. It is clear what choice is best for me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I am aware of the options I have in this decision.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I feel I know the advantages of each option.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I feel I know the disadvantages of each option.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I am clear about <u>how important</u> the advantages are to me in this decision.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I am clear about <u>how important</u> the disadvantages are to me in this decision.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	<i>Strongly Agree</i>	<i>Agree</i>	<i>Neither Agree Nor Disagree</i>	<i>Disagree</i>	<i>Strongly Disagree</i>
<b>9. For the main options I am considering, I am clear about which is <u>more</u> important to me (the advantages or disadvantages).</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>10. I am making this choice without any pressure from others.</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>11. I have the right amount of support from others in the making of this choice.</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>12. I have enough advice about the options</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>13. I feel I have made an informed choice.</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>14. My decision shows what is important to me.</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>15. I expect to stick with my decision.</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>16. I am satisfied with my decision.</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## Appendix 13: Decision Regret Scale

### Decisional Regret

Please reflect on your treatment decision. Show how strongly you agree or disagree with these statements by circling the statement from strongly agree to strongly disagree which best fits your views about your decision.

B1. It was the right decision.	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
B2. I regret the choice that was made.	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
B3. I would go for the same choice if I had to do it over again.	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
B4. The choice did me a lot of harm.	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
B5. The decision was a wise one.	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree

## Appendix 14: Preparation for decision making scale

## Services Evaluation

### Navigation service evaluation *(not on control questionnaire)*

Please indicate how satisfied you are with the question-listing support you received (check one box only please).

0	1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lowest										Highest

Please write any general comments of, or suggestions for improving the program:

---



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### Services Evaluation:

Did the services in the run up to your care...

	A great deal	Quite a bit	Some- what at		Not at all
1. Help you identify the questions you want to ask?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Help you organise your own thoughts about your cancer health care?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Help you think about how involved you want to be in treatment choices?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Prepare you to talk to your doctor about what matters to you?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## Appendix 15: Hospital Anxiety and Depression Scale

Patient code:

## Anxiety and Depression Scale

Please read each question carefully and **TICK** the **BOX** that comes **closest** to how you have been feeling in the **past week**. Do not take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought out response.

**1. I feel tense or 'wound up'**

- ☐ *Most of the time*
☐ *A lot of the time*
☐ *From time to time, occasionally*
☐ *Not at all*

**2. I still enjoy the things I used to enjoy**

- ☐ *Definitely as much*
☐ *Not quite as much*
☐ *Only a little*
☐ *Hardly at all*

**3. I get a sort of frightened feeling as if something awful is about to happen**

- ☐ *Very definitely and quite badly*
☐ *Yes, but not too badly*
☐ *A little, but it doesn't worry me*
☐ *Not at all*

**4. I can laugh and see the funny side of things**

- ☐ *As much as I always could*
☐ *Not quite so much now*
☐ *Definitely not as much now*
☐ *Not at all*

**5. Worrying thoughts go through my mind**

- ☐ *A great deal of the time*
☐ *A lot of the time*
☐ *From time to time but not too often*
☐ *Only occasionally*

**6. I feel cheerful**

- ☐ *Not at all*
☐ *Not often*
☐ *Sometimes*
☐ *Most of the time*

**7. I can sit at ease and feel relaxed**

- ☐ *Definitely*
☐ *Usually*
☐ *Not often*
☐ *Not at all*

**8. I feel as if I am slowed down**

- ☐ *Nearly all the time*
☐ *Very often*
☐ *Sometimes*
☐ *Not at all*

**9. I get a sort of frightened feeling like butterflies in my stomach**

- ☐ *Not at all*
☐ *Occasionally*
☐ *Quite often*
☐ *Very often*

P.T.O

Patient code:

**10. I have lost interest in my appearance**

- |  |   |   |   |
|--|---|---|---|
| <input type="checkbox"/> <i>Definitely</i> | <input type="checkbox"/> <i>I don't take as much care as I should</i> | <input type="checkbox"/> <i>I may not take as much care</i> | <input type="checkbox"/> <i>I take as much care as ever</i> |
|--|---|---|---|

**11. I feel restless as if I have to be on the move**

- |  |   |   |  |
|--|---|---|--|
| <input type="checkbox"/> <i>Very much indeed</i> | <input type="checkbox"/> <i>Quite a lot</i> | <input type="checkbox"/> <i>Not very much</i> | <input type="checkbox"/> <i>Not at all</i> |
|--|---|---|--|

**12. I look forward with enjoyment to things**

- |   |  |  |   |
|---|--|--|---|
| <input type="checkbox"/> <i>As much as I ever did</i> | <input type="checkbox"/> <i>Rather less than I used to</i> | <input type="checkbox"/> <i>Definitely less than I used to</i> | <input type="checkbox"/> <i>Hardly at all</i> |
|---|--|--|---|

**13. I get sudden feelings of panic**

- |  |   |  |  |
|--|---|--|--|
| <input type="checkbox"/> <i>Very much indeed</i> | <input type="checkbox"/> <i>Quite often</i> | <input type="checkbox"/> <i>Not very often</i> | <input type="checkbox"/> <i>Not at all</i> |
|--|---|--|--|

**14. I can enjoy a good book or radio or TV programme**

- |                                       |   |   |   |
|---------------------------------------|---|---|---|
| <input type="checkbox"/> <i>Often</i> | <input type="checkbox"/> <i>Sometimes</i> | <input type="checkbox"/> <i>Not often</i> | <input type="checkbox"/> <i>Very seldom</i> |
|---------------------------------------|---|---|---|



## **Appendix 16: Intention To Treat analysis of primary outcome measure**

### **Primary Outcome Measure: Decision Self Efficacy (DSE) Intention to Treat**

There was a non-significant main effect of the trial arm  $F(1,132)=2.46, p=0.119$ ; the rating of DSE did not differ significantly between groups. Bonferroni corrected post hoc test showed that the intervention group ( $M87.49, CI95\% 84.62-90.36$ ) overall scored higher on the DSE ( $M_{diff}=3.20, CI95\% -0.83-7.23$ ) when compared to the control group ( $M84.29, CI95\% 81.46-87.12$ ), although not significantly.

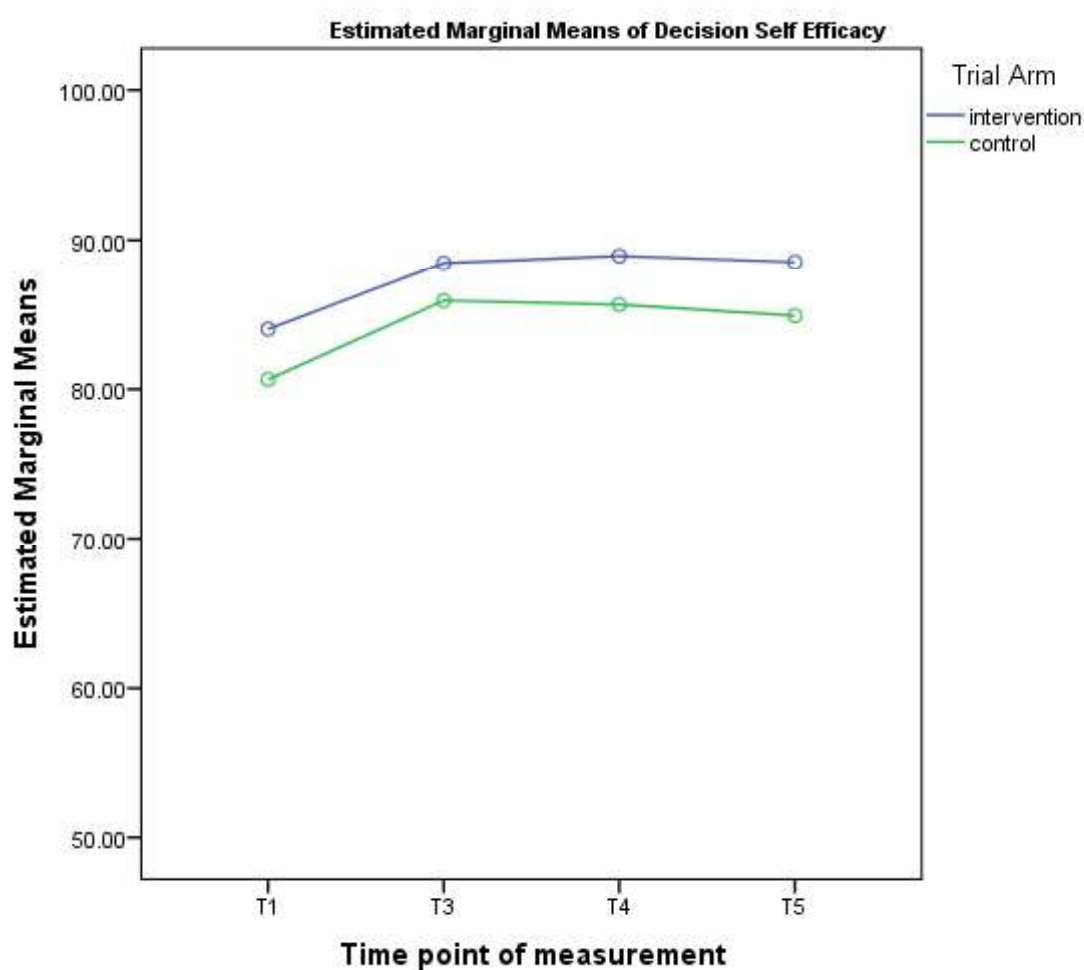
A significant main effect of time was found on the rating of DSE,  $F(1.99,369)=9.43, p=<0.001$ . Without acknowledging the trial arm participants were part of, the DSE was rated different according to the time it was completed. The Bonferroni corrected post hoc test showed that rating of DSE at baseline (T1) was significantly lower than the time points T3 ( $M_{diff}=-4.86, CI95\% -8.24 - -1.48, p=0.001$ ), T4 ( $M_{diff}=-4.97, CI95\% -8.52 - -1.42, p=0.002$ ), T5 ( $M_{diff}=-4.40, CI95\% -8.19 - -0.60, p=0.014$ ). All other changes in DSE score across time were non-significant ( $p>0.05$ ).

However, a non-significant Time x Trial arm interaction was found  $F(1.99,369)=0.89, p=0.914$ , the rating of DSE over time did not differ between intervention and control groups, see table 1 and Figure 1 below.

**Table 1.** Mean scores of the Decision Self-Efficacy scale for all responders over time T1-T5, per trial arm.

Time	Trial Arm	n	Mean	Std. Deviation
Baseline T1	Intervention	66	84.02	13.08
	Control	68	80.65	19.81
	Total	132		
T3	Intervention	66	88.46	11.32
	Control	68	85.92	12.71
	Total	132		
T4	Intervention	66	88.94	12.02
	Control	68	85.66	14.91
	Total	132		
T5	Intervention	66	88.53	11.42
	Control	68	84.93	15.51
	Total	132		

**Figure 1. Mean group DSE scores (ITT) by time**



## Appendix 17 – HGG invitation sheet

### Title of project: Patient Information Navigation Study

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Office address and telephone number

*Date*

Dear [*Patient's name*]

Thank you for your interest in the Patient Information Navigation Study which is currently being trialled at the [*Name of centre*].

The study is evaluating a new service called **Patient Information Navigation** which is designed to help you prepare for your consultation and provide you with personalised information about your health care, in the form of a CD and written summary of consultations.

I have enclosed an information sheet about the study.

A member of the study team will be contacting you in the near future to answer any questions you may have, and if you are happy to take part, take you through the consent process.

Thank you once again for your interest.

Yours sincerely

Sarah Shepherd  
Study Evaluator

## Appendix 18– HGG Consent form



### Title of project: Patient Information Navigation Study

## Participant CONSENT FORM

Principal Investigator: Dr. Belinda Hacking

	Please initial boxes
1. I confirm that I have read and understand the information sheet ( <i>Version 3</i> ) for the above study and have had the opportunity to ask questions.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3. I agree that the written information I provide can be stored with my name removed from all records and used in the presentation of the research. My data will not be used to identify me	
4. I agree to take part in three interviews throughout the study to talk about my experience of navigation.	
5. I agree that the audio information I provide in the interview can be audio taped, transcribed, stored with my name removed from all records and my words used in the presentation of the research. My words will not be used to identify me.	
6. I agree to take part in the study	
7. I agree for my GP to be informed about my participation in this study AND for a consultation summary to be sent to my GP (you do not have to initial this box, if you would prefer NOT to have your GP informed of your participation).	
8. I would like to be informed of the results	

\_\_\_\_\_  
Name of Patient                      Date                      Signature

\_\_\_\_\_  
Principal Investigator                      Date                      Signature

*1 Copy for the patient, 1 Copy for the principal investigator*

## **An Evaluation of a Patient Information Navigation Service (*neuro*)**

### **Patient Information Sheet**

**If you would like further information about this study, or would like to  
volunteer to participate, please contact:**

**Sarah Shepherd**

**Phone:**

**Email:**

We are inviting you to take part in a research study. We are studying whether a new approach to helping patients discuss their concerns with their doctor is helpful.

#### **What is the Purpose of this Study?**

This study is trialling Navigation, a way of supporting patients to gather and remembering information about their health care. Navigation has been successful in the USA. Results of the trial will help to inform practice.

#### **Why have I been asked to take part in this study?**

You have been asked to participate in this study because you are attending an appointment to discuss your surgery. It is up to you whether you take part or not. If you decide to take part, you will be asked to sign a consent form. If you decide to participate now but change your mind later, you can withdraw without giving a reason. Your decision to take part does not affect your treatment in any way.

#### **What will happen if I take part?**

If you decide to take part and agree to the statements on the consent form you will be assigned a ‘navigator’ and an appointment to meet with them. In this meeting the Navigator will help you think about your questions for your upcoming appointment. This can happen for up to 4 different appointments where relevant to your healthcare. With your permission, the navigator will accompany you to your consultation and will note the answers to your questions, as well as other important information. You will be provided with this summary and a digital audio recording of the consultation (CD). The summary will also be sent to your GP, with your consent.

Throughout the study you will also be asked to take part in 3 interviews to talk about your experiences in consultations. This will be at 3 different time points over the next 6 months. They will be arranged at your convenience.

It is your choice if you would like a relative or someone who is involved in your care outside of the health profession to be involved in this process.

### **What do I have to do?**

The meeting with the navigator will take 30 minutes; this can be done by phone or at the hospital. The interviews can also be done over the phone and approximately 45 minutes, or however long you want to talk for.

### **What are the potential benefits and disadvantages of taking part?**

This study could help us to improve the quality of our services for future patients. By taking part, you will also be able to have a summary of your own meeting with your doctor as well as a digital audio recording of the meeting.

If any part of the Navigation or interviews make you feel uncomfortable or upset, you are free to decline to answer any questions, or to discontinue your participation at any time.

### **What will happen if I don't want to carry on with the evaluation?**

If you do not want to continue with the evaluation part way through, we may still use the data that you have given. However, you are free to withdraw from the evaluation altogether and we can remove all your data from the evaluation if you ask. If you choose to do this you do not have to give a reason for your choice. Your treatment will not be affected in any way by withdrawing from the study.

### **What will happen to the results of the evaluation?**

All participants will be offered a short newsletter at the end of the study. The results of the study will be disseminated in peer reviewed journals, professional publications and presentations made at relevant conferences. Results will be reported in such a way that preserves anonymity.

### **Who is organising and funding the evaluation?**

The evaluation of this study is being conducted by a team based at Coventry University. If you have any concerns or questions about this evaluation or the way it has been carried out, you should contact the principal researchers (Sarah Shepherd (tel number) or Dr. Belinda Hacking (tel number)).

**For further information about the study or if you would like to volunteer to take part, please contact:**

**Sarah Shepherd – phone xxx or email xxx**

## Appendix 20 – The clinician consent form



**Title of project: Patient Information Navigation Study**

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### **Clinicians CONSENT FORM**

Participant study code:.....

Principal Investigator: Dr. Belinda Hacking

Consenting statements	Please tick boxes
1. I agree to take part in an interview to talk about my experiences of the Navigation intervention.	
2. I agree that the audio information I provide in the interview can be audio taped, transcribed, stored with my name removed from all records and my words used in the presentation of the research. My words will not be used to identify me.	
3. I understand my participation is voluntary and I am free to withdraw at any time.	

---

*Name of Participant*

---

*Date*

---

*Signature*

## **Appendix 21 – The interview schedules**

### **Interview schedule with patients**

Researcher introduces self and aims of the interview:

- To ascertain in-depth understanding of patient perspective of consultation
- To ascertain patient satisfaction with consultation

Informs the patient the interview will take approximately 30 minutes, or however long they have something to talk about. The questions below are not intended to be spoken verbatim but provide examples of questions and topics to cover.

Ask the patients for permission to audio-record the interview. Begins;

“Could you describe to me the consultations you have attended at the Cancer Centre since your surgery was complete? Let’s start from the most recent and work back, or whichever way you prefer”

1. Did you prepare for your consultations?
  1. In what way? Did you receive any help?
  2. Why did/didn’t you prepare?
  3. If you prepared, did this help/how? If you didn’t prepare, do you feel there would have been any benefit to preparing?
  4. What did you expect your role to be as a patient in consultations?
2. With regards to the information you obtained...
  1. Where would you say your main source of information was?
  2. How did you find this source of information for telling you everything you needed/wanted to know? Did you feel like everything was covered?
  3. What kind of information did you feel was important? How easy was it to gather this information? Was there any information you would have liked more of?
3. Thinking about your consultations
  1. How satisfied were you with your consultations? Why?
  2. How did you find gathering information in these consultations? Why?
  3. How did you find asking questions of your consultants? Why?



4. Did you feel the consultant understood you and your situation as an individual? Why?
  5. Do you feel the consultant engaged with you and asked you questions?
  6. What do you feel the role is for a patient within their consultations?
4. Decision Making
1. Do you prefer to make the choices, the dr. to make the choices or for it to be shared?
  2. Did you feel you had a choice with regards to treatment when you were in your consultations? Please explain this. Did you want this choice? Did you feel informed enough to make this choice?
5. Your journey
1. Looking back
    - i. Treatment – how informed have you felt?
    - ii. were you happy with the treatment choices you made?
    - iii. Have you felt well enough informed about self-management issues such as diet, exercise, stress, alternative and complementary therapies?
    - How has this impacted the way you have coped?

6. Is there anything else you would like to add to the interview?

Navigation Materials – intervention patients only

- a. How did you find Navigation?
- b. How was having the CD? Summary? did you use them? when / why / how
  1. Did you ever share this CD / summary with anyone?
  2. Have you used them with your GP?
- c. Are there aspects of Navigation that have been more helpful than others?
- d. How did you find having another person in the consultation with you?
- e. Would you change the service in any way? How?
- f. How did you feel about speaking with a Navigator to create your list of questions
- g. Did you feel the consultant you had used your question list appropriately?

*Ask for verbal consent to transcribe the interview. Thank the participant for their time*

## **Appendix 22**

### **Clinician Interview Schedule**

Begin – introducing aims are to understand the clinician’s perspective on the intervention.

#### **1. Clinicians understanding of the intervention**

- What do you understand to be the aim of the intervention?
- What do you understand to be the role of the navigator?
- Do you think the intervention met these aims? How why

#### **2. Clinicians use of the intervention materials –explain materials –CP/CS/CR**

- How useful did you find the consultation plan? Did you read it? If yes, when? If no, why? Did you implement the plan during the consultation? Why/why not? How?
- Do you see a benefit for recording consultations? For patients? For clinicians? Yes? Why/how
- Did you have an opportunity to read the consultation summary after the meeting? Were you satisfied that it was an accurate reflection of what was said during the consultation?

#### **3. The impact of the intervention on the consultation PATIENT**

- Looking back how do you think the consultations with patients who were receiving the intervention went?
- How do consultations with patients who have not received this intervention compare to those where they have? What are the differences? why
- What were your general feelings about ...
  - a. Was there an impact upon intervention patient’s participation in your consultations?
  - b. Was there a difference in how intervention patients engaged your consultations compared to usual care consultations?
  - c. Was there a difference in understanding the information which you felt was important for them to remember compared to usual care consultations?
  - d. Did you the intervention impacted on treatment decision making?

#### **4. The impact of the intervention on the consultation PRACTICAL**

- In general, were you happy with the way intervention consultations went? Why/why not? What do you think the benefits of this intervention are?
- Did the presence of the navigator affect the consultation?
- How did you feel about the consultation being recorded? Have you requested a copy of the recordings at any point?
- Do you think the intervention could have been improved in any way? If yes, how? Why?
- Do you feel the time taken for consultation was affected?

#### **5. Impact of intervention on clinicians practice**

- Has the intervention impacted upon how you conduct your consultations outside of the study?
- Has the study highlighted anything for you in terms of practice?

#### **6. Relevance within practice**

- Do you feel the intervention has a place in the normal care pathway for cancer patients?
- Do you feel that there are barriers to supporting patients in making treatment decisions? How might these be overcome?

**Thank for participation and time in interview and intervention.**

**Appendix 23– An example from one Navigation trial participants’ transcript to demonstrate the indexing stage of framework analysis.**

**Colour key:** Green =preparation for consultation, Blue= Recall and understanding, Yellow= Information exchange, Purple = decision making

P: Yes, I had been, Mrs X, she was a navigator, she came to the consultant with me and she was good as well, it was good cause I live on my own, I don’t have a partner, so you know when things like that are happening you’re not actually taking it in so she was good, she transcribed it all, she put it on DVDs and everything for me, so yes that did help, prepared before I went in any questions I wanted to ask him, if I forgot she was reminding me, sort of thing, so yeh, it was really useful to have a navigator I must admit.

**I: So, do you feel...how do you feel that helped you that...creating the questions yourself?**

P: It did help and also she could prompt me as well cause she was thinking about saying the things that I hadn’t thought about, you know, so yes it was helpful all round.

**I: That’s good.**

P: That’s great, it’s just cause I have no other means of support as well.

**I: And, so during the consultation, you used the question list?**

P: Yes, I did, I have yeh.

**I: So, was that just to refer back to?**

P: It was, yeh, and I think in the consultancy also got a copy beforehand. They all requested something’s going after, for then he had a chance to prepare his answers as well.

**I: So he made use of it as well?**

P: Yes, he did. It worked all round for everybody.

**I: So, did you feel you got more out of it by the two of you having the same information in front of you?**

P: I think so, yes I think you get more out of it cause I see your notes. You can’t quite believe it going through this , so that kinda keeps you ....sort of focused a bit really.

**I: Yeh, that’s good and how did you feel having, like X in the room with you?**

P: That was fine, no problem at all. She was very discreet and she’s a great person anyway, so...you know she’s very discreet, she didn’t really interfere at all.

**I: How did you feel about having it recorded as well, when you were at the consultation?**

P: At the time it was useful. I mean all I think I .... all what I did was listen to recordings initially after the first consultation and after that. I’ve still got them but I never...I never listen to them again. But I think they were useful, just in case there’s something you’re not quite sure about, they’ve mentioned. You think what did he say there? I can’t quite remember, so yeh, that was quite useful.

## Appendix 24B – A brief excerpt of the charts created for each theme through framework analysis

Participant	Preparation for the consultation	Info exchange	Recall and understanding	Decision Making
Rose, intervention trial participant	So it was all already prepared, the questions were there and the doctor answered them for me without them having for me physically having to say it in the room. 56-7 discussing it beforehand helped me to verbalise what was going on but then she would reiterate it, make me feel more confident about what I was thinking and reassure me and put it into words that I couldn't physically 81-3	gave me the confidence to believe that the questions that I had weren't stupid, they were quite reasonable for me to feel like that and to ask those questions. 77-79 she (dr) seemed to know... well she didn't seem to know, she had the summary there as well before I even said something she was and yes and she was so reassuring, she was absolutely brilliant. 376-7	I referred to the sheet that was sent out from the Navigation study after the appointment, I referred to that a couple of times because the side effects were all listed there for me 214-7 when things were getting a bit stressful I could look at that [SUMMARY] and say right I get those, the eight cycles of that, that means that, that means this. 222-4 I couldn't remember half the things that were said. So a couple of times I did listen to the CD and I had the sheet in front of me 362-5	She didn't just say to me well no don't... I don't know what would normally happen but it felt as if she went above and beyond just to reassure me of what my choices were. 176-81 But then it was quite a simple decision to make, when you weighed up the pros and cons of what was going on given the information which is provided by the consultant, the way that my husband felt would mean... basically just weighing everything up. 412-5 your role is to listen and to trust what you're being told is going to make things better 521-2
Mick, High grade glioma	there was questions that I don't think I would have asked if I hadn't had the structure. 310-4 So on that day I don't think I would have been able to structure my thoughts and my questions and ask them without having them written down in front of me, it was just such an overwhelming situation that I	But the fact that there was still a lot more questions written down, it almost immediately brought me back to listen to her and, not forgetting about what she said, but set it aside for the rest of the discussion so I could hear what she was talking about. 328	Because I look at it now and there's so much information there that I needed to know, but at the time, when I remember what state I was in, it would have been, if I hadn't had the structure I think it would have just been a shock. You know, the statement that Dr xx made about it not being a curable condition, that	Because it very much seemed like it was a clinical judgement, you know, and it's the clinical judgement they make for everyone. You know, "We're going to give you radiotherapy because it's the best treatment available. And that's it. And then, if you survive a year or so, well, there might well be side-effects down

	just wouldn't have been able to do it without the support of the navigator. 669-75		would have been me – 320-4 I think it does come as a package. Yeah, I mean, I suppose the one thing that I haven't found that useful has been the CDs, really because I don't want to listen to them. 630	the line 540
Barry, control trial participant	I guess as everyone does now, we look on the internet and that kind of informs the discussion that we have with the consultant 237 you know realised that these consultants are very professional people and they would respond to...almost like a structured discussion in a right way.321	I think the consultations with Miss X and with Doctor Y have been very good, very informative. I mean they're ready to answer any questions; they're quite clear about what's happening, so I've always felt able to discuss with them what's going on21-22 I would say all these consultations, you know...each of the consultants was given some information and was able to ask questions and then they made recommendations I'd go along with that. I don't really feel, that I would you know second guess what they recommend. 98	my wife comes with me and will take notes, I think the way it works is that I generally ask the questions and the fall outs and she will sort of write down the answers, cause I think it's quite important to get those down quite promptly, while they're still fresh. 271, you know when you ask a question, presumably it's an important question to you, you kind of listen at the time and you hear and understand it but I think you do need the actual words that were spoken to look back at, ... rather than kind of the impression that you might have taken away. 283 I think there's a risk with it, that you'll kind of get a bit overwhelmed by all the information there is but....I think as some said, you just switch off and say: well I've done enough of this. 394	I know they have the multidisciplinary meetings but you know, for a quite a while, it wasn't clear to me what's happening or if anything was happening. 70 It was effectively a recommendation. I mean I guess...I'm just thinking...I think at that stage, I was just really referred to Doctor Y and had a discussion with her and she explained why the decision to treat was recommended. 74 I thought I understood enough about it, that they wanted to...you know, reduce the tumour. That was really, you know, kind of the whole point of it, I think, so I was happy to go along with recommendations. 81 I mean the biggest thing I suppose part of this is...is unknown, you know, kind of what's happened what is going to happen 712

